PB83-262345

Regulatory Impact Analysis for New Chemical Reporting Alternatives under Section 5 of TSCA (Toxic Substances Control Act)

ICF, Inc., Washington, DC

Prepared for

Environmental Protection Agency, Washington, DC

May 83

U.S. Department of Commerce
National Technical Information Service
NTIS

50272-101

REPORT DOCUMENTATION PAGE

1. REPORT NO. EPA 560/4-83-002

2.

3. Recipient's Accession No. PB83 262345

4. Title and Subtitle

Regulatory Impact Analysis For New Chemical Reporting Alternatives Under Section 5 of TSCA

5. Report Date May 1983

6.

7. Author(s) Robert C. Dresser, Stuart L. Fribush, William M. Mendez

8. Performing Organization Rept. No.

9. Performing Organization Name and Address

ICF Incorporated
1850 K Street, N.W., Suite 950
Washington, D.C. 20006

10. Project/Task/Work Unit No. Task No.11

11. Contract(C) or Grant(G) No.

(C) 68-01-6287

(G)

12. Sponsoring Organization Name and Address

Office of Pesticides and Toxic Substances
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

13. Type of Report & Period Covered Final Report

14.

15. Supplementary Notes

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16. Abstract (Limit: 200 words)

This report presents the results of analysis of various information reporting alternatives for the Premanufacture Notification (PMN) process under section 5 of TSCA. The PMN process is the method by which the Office of Toxic Substances of EPA reviews data submitted by manufacturers and importers of new chemicals. The data must be submitted to EPA for review at least 90 days prior to when actual manufacturing or import begins.

The premanufacture notification and review processes are statutory requirements of TSCA. However, TSCA does not mandate the use of a particular reporting form, nor does it specify data to be submitted. Based on experience gained during four years of operation on an interim basis, the Agency developed a PMN reporting rule that included a mandatory form. The report compares the economic costs of these provisions to those of three alternative reporting methods. The analysis shows that the private costs of the rule range from $5 million to $13 million annually and that Agency PMN review costs are about $7 million per year. Although the data are incomplete, adverse chemical innovation effects associated with the PMN rule are not believed to be large. The PMN process conducted under the final rule is expected to maintain the Agency's effectiveness in preventing adverse human health effects.

17. Document Analysis a. Descriptors

TSCA Section 5 Premanufacture Notification Requirements
Regulatory Impact Analysis

b. Identifiers/Open-Ended Terms

c. COSATI Field/Group

18. Availability Statement

19. Security Class (This Report) Unclassified

20. Security Class (This Page) Unclassified

21. No. of Pages 377

22. Price

PB83-262345

REGULATORY IMPACT ANALYSIS FOR NEW CHEMICAL REPORTING ALTERNATIVES UNDER SECTION 5 OF TSCA

Prepared for
Economics and Technology Division
U.S. Environmental Protection Agency

May 10, 1983

REPRODUCED BY
NATIONAL TECHNICAL INFORMATION SERVICE
U.S. DEPARTMENT OF COMMERCE
SPRINGFIELD, VA. 22161

ICF INCORPORATED International Square
1850 K Street, Northwest, Washington, D. C. 20006

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PREFACE

The attached document is a contractor's study done with the supervision and review of the Office of Pesticides and Toxic Substances of the U.S. Environmental Protection Agency (EPA). This study provides support for EPA's final new chemical reporting requirements under section 5 of the Toxic Substances Control Act (TSCA).

This report is being released concurrent with publication in the Federal Register of the final rule establishing premanufacture notice requirements and review procedures for new chemicals under section 5 of TSCA. The classification of this rule as "major" under Executive Order 12291 required that EPA prepare this Regulatory Impacts Analysis. The Analysis has been extensively reviewed within EPA and the Office of Management and Budget. The Analysis is based largely on previous assessments of the economic effects of the proposed rule and on the Agency's experience with the premanufacture notification program which has operated on an interim basis since July 1979.

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EXECUTIVE SUMMARY

Section 5(a)(1)(A) of the Toxic Substances Control Act (TSCA) requires manufacturers and importers of new chemicals to provide the Environmental Protection Agency (EPA) with notice of their intent to manufacture or import such substances at least 90 days prior to when actual manufacturing or import begins. Any chemical not listed on the TSCA Chemical Substances Inventory is considered "new" for premanufacture notice (PMN) purposes. This report presents the results of analysis of the regulatory impact of several alternative information requirements. The analysis was used by the Agency to help guide decision-making as to what the final reporting requirements should be. Indeed, this report represents the written record of this analysis. The careful review of three alternatives resulted in the Agency modifying one of the forms to create a fourth alternative -- the FINAL form. This form and accompanying instructions and regulations will replace the reporting guidelines for the new chemical review program, which has operated on an interim basis since 1979.

The premanufacture notification and review processes are statutory requirements of TSCA. However, TSCA does not require either that specific PMN requirements and processes be stated in a rule or that the information be provided in a particular form. Based on the experience developed during the first several years of operation, the Agency has determined that issuance of a final PMN rule and form is in the best interests of all concerned parties. The final rule sets out the information which the Agency has determined is necessary to determine whether the commercial introduction of newly developed chemicals will present an unreasonable risk to human health or the environment. By requiring the use of a final form, the Agency will be better able to conduct complete reviews within the statutory 90-day period. In addition, companies will benefit to the extent that they will be aware of all information requirements from the start; thus, uncertainty will be reduced to a significant extent.

Over the past five years the Agency considered many alternatives for the PMN rule. Three alternatives were considered initially in this analysis. As a result of analysis performed in support of this study, and other analyses, a fourth form was developed. The four forms are differentiated by the scope of the information requested. They are:

- EPA79 Form. The EPA79 form (an interim proposal developed by EPA in 1979) requires submitters to provide the most information. The major areas for which information is sought are: submitter's identity, chemical identity, generic names, production and marketing data, transport, risk assessment, detection methods, human exposure and environmental release at sites controlled by the submitter and at sites controlled by other firms manufacturing the chemical, consumer and commercial use exposure, physical and chemical properties, health and environmental effects data, confidentiality attachment, a Federal Register notice, and any other information the submitter volunteers. This form should cost $1,800[1] to $14,600 to complete.

- CMA79 Form. The Chemical Manufacturers Association developed a proposed PMN form based on the principle that section 5(d) of TSCA provides an all-inclusive list of the information that a PMN is to contain. This form contains mandatory and optional parts. Mandatory parts include submitter's identity, chemical identity, production and use data, Federal Register notice, list of health and environmental data, and information in the submitter's possession regarding industrial sites not controlled by the submitter. Optional parts include risk assessment information (risk analysis, related chemicals, general industrial hygiene program, specific safeguards, process chemistry, transport data, and additional risk-relevant information) and additional information on worker exposure and environmental releases. The mandatory portion of the form should cost between $1,300 and $6,400 to complete.

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[1] These estimates are different from previously reported estimates because they have been increased to reflect labor costs in December 1981.

- EPA82 Form. The information sought under this form includes: submitter's identity; chemical name; identity and molecular structure; simplified production and marketing data; simplified flow diagram; and simplified worker exposure, release, and disposal estimates (relative to the October 1979 proposal). It is estimated to cost $1,200 to $6,200 to complete.

- FINAL Form. This form is very similar to the EPA82 form. It adds information about worker activity exposure, general information about sites controlled by others, and clarifies other sections. It is estimated to cost $1,300 to $7,500 to complete.

The analysis reported here draws on many previous analyses and a data base of approximately 500 PMN submissions to estimate the health effects and economic impacts of the alternative reporting requirements. Using these data four costs which firms incur were computed. These costs are:

- Direct filing costs - i.e., the cost of gathering the needed data, completing a PMN submission and filing it with EPA.

- Confidentiality - firms may choose to claim that data contained in a PMN are confidential. If the claim must be substantiated, the cost of completing a PMN is increased.

- Delay - the TSCA-imposed 90-day PMN review period may delay sales of a chemical if a ready market exists or may cause a sales loss if a prospective customer purchases an alternative product.

- Cost of EPA-Induced Restrictions - During the PMN review EPA often suggests that actions be taken to reduce the possible health hazard. The cost of these voluntary actions is a cost of the reporting requirement.

Taken together, these costs reduce the expected rate of return on new chemical substances and increase the economic risk incurred by manufacturers. Since many new chemicals are produced and sold in small quantities and must be price-competitive with existing products, the result may be a depressing impact on the rate of new chemical innovation, an adverse effect of potentially major significance.

The total annual cost to industry and EPA of each of the options is presented in Exhibit ES-1.

EXHIBIT ES-1

ANNUAL COSTS OF REGULATORY OPTIONS*
(Thousands of 1981 Dollars)

	EPA79	CMA79	EPA82	FINAL
Total Industry Costs				
Form Filing Costs	$1,620-$13,140	$1,170- $5,760	$1,080- $5,580	$1,170- $6,750
Confidentiality Costs	$1,580	$321	$330	$330
Delay Costs	$1,055- $1,843	$1,055- $1,843	$1,055- $1,843	$1,055- $1,843
Restrictive Actions	$2,605- $4,038	$2,308- $3,578	$2,373- $3,679	$2,605- $4,038
Total	$6,859-$20,601	$4,854-$11,502	$4,838-$11,432	$5,160-$12,961
Total EPA Costs				
Review	$6,955	$6,955	$6,955	$6,955
Total Costs	$13,815-$27,556	$11,809-$18,457	$11,793-$18,387	$12,115-$19,916

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*Assumes 900 new PMN chemicals per year.

As shown by the Exhibit, the annual real resource costs of the program using the FINAL form are $12.1 to $19.9 million with almost $7 million being government review costs. These costs are close to the costs of the EPA82 and CMA79 form and considerably less than the cost of the EPA79 form.

EPA has engaged in efforts to exempt certain types of chemicals from the standard PMN process. These efforts have resulted in one final and two proposed PMN exemption rules. As a supplement to the analysis, the cost savings from the photographic exemption and the proposed low volume, site-limited intermediate, and polymer exemptions have been determined. On average an exemption notice costs about one-twentieth of the cost of a PMN. Thus, the total cost to industry of the PMN program would decline by 21-29 percent to between $4.1 and $9.2 million. The exemptions would also reduce EPA's review costs by about $2 million.

The benefits of the alternative forms are primarily the benefits of having sufficient information to make correct decisions. Based on an EPA analysis of previous situations in which the Agency encouraged voluntary control actions by submitters, it appears that the EPA79 form is more likely to provide sufficient information for regulatory decisions than either the EPA82 or CMA79 form. The FINAL form is designed to ensure the same outcomes for hazardous chemicals as the EPA79 form.

The innovation effects of the PMN program appear to be selective. Based on data from several industry commissioned surveys and data in confidential PMN files, it appears that since the program became effective, there has been no statistically significant change in the number of new chemicals introduced by the largest companies; but there may have been a decline from small companies. Although the decline in new product introduction by small companies is of concern, the decline, by two estimates, reduces total industry profits derived from new chemicals by less than five percent (the uncertainty about the estimate is much greater than five percent).

As with most regulatory programs, the small business effects of the section 5 program are of potential concern. However, regulatory costs to firms with less than $30 million in annual sales are estimated to be $340 thousand to $790 thousand. This represents less than 1% of sales for these companies and between 0.9 and 2.1% of their profits. For firms under $100 million in annual sales, costs are estimated to be $639 thousand to $1,486 thousand. This represents less than 0.1% of sales and 0.3-0.6% of profits for these firms. The proposed exemption rules are expected to result in a savings of 11 to 35% for firms under $30 million in annual sales. For firms under $100 million, the exemption related savings are estimated to be in the range of 11 to 33%.

To conclude, the FINAL form should cost industry about $5,160 to $12,960 thousand annually, and it should cost EPA $6,955 thousand per year (variable review costs) to run the program. The kinds of benefits achieved since the program began in 1979 (i.e., adverse human health effects avoided) should continued to be realized when the FINAL form is adopted. The Agency believes that the FINAL form will achieve the maximum net benefits to society from the PMN program.

CHAPTER I

INTRODUCTION AND APPROACH

This chapter is presented in two sections. Section A presents the background and scope for this analysis including a brief history of the implementation of section 5 of the Toxic Substances Control Act (TSCA), the requirements of Executive Order 12291, and the purpose of this analysis. Section B briefly describes the general approach of this analysis and points out its strengths and limitations.

A. BACKGROUND AND SCOPE

1. Brief History of Rulemaking Under TSCA Section 5

Section 5(a) of TSCA requires that manufacturers and importers of new chemicals submit information to EPA at least 90 days before such manufacture or importing begins. Section 5(d)(1) specifies that this submission shall include the following information, to the extent that is reasonably ascertainable:

- trade name, chemical identity, and molecular structure;
- proposed categories of use;
- estimates of the amount to be manufactured or imported for each proposed category of use;
- a description of the byproducts resulting from manufacture, processing, use, or disposal;

- estimates of the number of workers exposed and the duration of their exposure; and
- a description of the proposed method of disposal.

In addition, the submission must contain any test data concerning the environmental and health effects of the new chemical in the submitter's possession or control, and descriptions of any other data concerning such effects that are known to or reasonably ascertainable by the notice submitter.

Section 5(h) provides for exemptions from the information requirements for certain new chemicals. Four primary types of exemptions are addressed in the statute:

- test-marketing exemptions;
- exemption from the requirement to submit health and safety data;
- exemptions for research and development chemicals; and
- exemption by rule (upon application) for chemicals not posing an unreasonable risk.

Regulations to implement section 5 reporting requirements for new chemical substances were first proposed on January 10, 1979 (44 FR 2242). Included in the proposed rules were detailed notice forms. Comments were received in response to this proposal, and the regulations were ultimately reproposed October 16, 1979 (44 FR 59764). Section 5 is currently being administered under an EPA interim policy initially announced on January 10, 1979 and modified on May 15, 1979 and November 7, 1980. This policy does not require completion of a specific notice form, although submitters may use the form included in the 1979 EPA interim policy (herein referred to as EPA79), the form suggested by the Chemical Manufacturers Association in comments to the January 1979 proposal (herein referred to as CMA79), or any other format.

During the past four years the Agency has considered, analyzed, evaluated, and dismissed many possible information requirements. In 1980 the Agency evaluated a set of information requirements that were known as the "minimum guidance," (see ICF 1980) but after analysis rejected this alternative. In early 1981 a "final form" similar to the EPA79 form was analyzed. It too was found deficient. During 1980 and 1981 over 1,000 PMNs were submitted to EPA under the interim policy and much was learned about the kinds of information needed to assess the risks posed by them. After substantial data analysis of PMNs, a form was developed in the spring of 1982 that was considered to be potentially optimal.

This paper reports the results of an analysis of the spring of 1982 (EPA82) form's costs and benefits. It compared EPA82 to CMA79 and EPA79, and in the final chapter reports on modifications to EPA82 made as a result of this and concomitant analyses performed during the summer and fall of 1982. These analyses and modifications resulted in the development of the FINAL premanufacture notification form.

As mentioned above, four regulatory alternatives for reporting requirements were considered. These included: (1) the EPA79 information requirement, (2) the proposed CMA79 information requirement, (3) the EPA82 information requirement, and (4) the FINAL form. (All four of these alternatives are described in subsquent chapters.) The first three reporting alternatives have been analyzed in light of two PMN exemption scenarios. The first exemption scenario is the pre-1982 situation, in which no exemption rules had been promulgated. The second exemption scenario includes all of the recently-developed exemption rules, which represent a reduced reporting burden for low volume chemicals, site-limited intermediates, polymers, and photographic chemicals (the instant photograhic chemical rule is now final). The proposed exemption rules are described in Chapter IV.

2. Executive Order 12291

Executive Order 12291, issued February 17, 1981, requires regulatory impact analyses (RIAs) of major regulations and expands the oversight role of the Office of Management and Budget. Major regulations are defined as any regulation that is likely to result in any of the following:

- an annual effect on the economy of $100 million or more;
- a major increase in costs or prices for consumers, industries, or governments;
- significant adverse effects on competition, employment, investment, productivity, innovation, or international trade.

Although the direct costs of compliance with section 5 are not likely to trigger the $100 million annual effect criterion, substantial controversy exists regarding the effects of section 5 on innovation in the chemical industry.[2] Therefore, EPA has chosen to prepare a regulatory impact analysis of section 5 requirements to address these concerns. In this analysis alternative approaches for implementing the requirements of this section are considered. For each feasible alternative, costs and benefits are analyzed.

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[2] For further information, please refer to CWPS 1981, Heiden and Pittaway 1982, NERA 1981, and CMA 1981.

3. Purpose of This Analysis

The purpose of this analysis is to provide objective information on the costs and benefits of the various reporting alternatives under consideration for implementing section 5 of TSCA. This information is needed for regulatory impact analysis under EO 12291. The specific information provided is as follows:

- direct costs imposed by section 5 rules under each of the regulatory options (Chapters III and IV);
- effects of the regulatory alternatives on innovation (Chapter V) and small business (Chapter VI); and
- an assessment of the benefits of each regulatory option, specified in terms of the number of chemicals identified as capable of posing human health or environmental risk under each option and their relative health and environmental risks (Chapter VII).
- a discussion and analysis of the FINAL information requirement developed after considering the analysis performed in Chapters I-VII (Chapter VIII).

B. GENERAL APPROACH

The general approach used in this analysis for estimating costs, innovation effects, and benefits is briefly explained in this section. For each of these three types of effects, the section explains: (1) what was included in the analysis, (2) how estimates were made, and (3) limitations.

1. Direct Costs of Compliance

The PMN program imposes direct costs on submitters and EPA that are incurred in filing a PMN submission. For submitters, these direct costs include:

- submission costs--the direct out-of-pocket costs of compiling and submitting information under section 5.

- delay costs--the reduction in the present value of the profit stream for the new chemical because of delayed introduction into commerce.
- confidentiality costs--costs associated with maintaining the integrity of confidential business information, including out-of-pocket costs for substantiating confidentiality claims and the costs of disclosure.
- cost of restrictive actions--after the submitter has filed a section 5 notice, it is possible that the submitter will have to take additional actions based on EPA's review.

In analyses conducted previously in support of EPA's section 5 rulemaking (ICF 1980), it was observed that there was a great deal of uncertainty (i.e., the variance was high) regarding each of these four direct costs incurred by submitters. This was true because submitters were not sure how EPA would implement the program, and thus it was not possible for submitters to build PMN costs into their decisions to market new chemicals with much confidence. However, the PMN program has been in effect for about three years and much of this uncertainty has been removed. Three years worth of historical PMN submissions also provide an objective data base for estimating section 5 costs. In this analysis, it was possible to use historical PMN submissions to provide estimates of the actual costs incurred by submitters. In addition, other analyses have been conducted which help clarify these costs (NERA 1981 and CMA 1981). (Chapter II provides detailed explanations of the nine main data sources used.) Thus, direct costs can now be estimated with far greater confidence. The estimates of direct costs to submitters appearing in Chapter IV reflect this greater confidence.

Throughout this analysis we refer to the "PMN impact." This term means all factors (not just measurable costs) that affect a submitter's decision to proceed to commercialize a new chemical when faced with the section 5 regulations.

The cost estimates in Chapter IV focus on the direct costs associated with the PMN program. These are the costs which directly contribute to the PMN impact: submission of information, delay, confidentiality and restrictive actions. The direct cost estimates of Chapter IV do not include indirect economic effects that result from submitters having to incur these direct costs. The major indirect economic effect is reduced innovation, which is addressed in Chapter V. Time and resource constraints prohibited the detailed analysis of other indirect economic effects such as price effects, employment effects, international trade effects, and concentration effects. However, indirect effects are clearly a function of direct effects. Therefore, concentrating available analytical resources on developing the best possible estimates of direct costs, innovation effects, and changes in health and environmental risk helps ensure the selection of the least burdensome alternative which meets regulatory objectives.

Also not included in the estimates of direct costs are costs of actions induced by section 5 rules (as opposed to actions required by section 5 rules). The major induced actions are additional testing performed by submitters. These costs have not been included in the estimates of direct costs of the PMN program because section 5 requires no testing.

Costs to EPA have been included in the direct cost estimates of Chapter IV. These include the costs of evaluating the information submitted, including the costs associated with processing confidentiality claims.

2. Effects on New Chemical Introduction

The general approach used to estimate the effects of the section 5 program on new chemical introduction was to hypothesize the steps in the research and development process where the section 5 program might have an effect and then to review recent studies to determine whether these effects are taking place. In addition, we explore the effect of submission costs on the profitability of new chemicals and the resulting likelihood of development of such chemicals given the burden imposed by PMN costs.

3. Health Implications of Regulatory Alternatives

Chapter VII compares the reporting alternatives in terms of differences in the magnitude of health effects associated with newly-introduced chemicals which may be introduced if any one of the three alternatives are routinely used. The first step in this analysis was to identify those chemicals that potentially would have adverse health effects and which would be treated differently under the different alternatives. Clearly, chemicals which were not expected to be harmful would not be expected to produce adverse health effects under any alternative. A set of approximately 70 chemicals was identified for which EPA had expressed concern about health or environmental effects.

The second step was to determine the health effects associated with these chemicals. Then it was necessary to determine the change in health effects based on the different approach EPA would have taken to regulate (or not regulate) the chemical. Expected results for these chemicals are provided in Chapter VII.

The major limitations in this analysis arise from the necessity of predicting what the actions of EPA and PMN submitters would have been in the hypothetical situation in which an alternative form was submitted. This analysis was based on a review of PMN submissions conducted by EPA personnel. While this review is believed to be accurate and reasonable in its findings, it is conjectural in nature and does not account for possible changes in submitter strategy that might have occurred had an alternative form been used. Finally, the health effects analysis is based solely on exposure and toxicity data from PMN files.

In the next chapter data sources are explained. This chapter is followed by two chapters developing the economic costs of the alternatives. Chapter V explores the innovation effects, Chapter VI the small business effects, and Chapter VII the incremental benefits of the alternative forms. Chapter VIII discusses the FINAL form that was developed after reviewing this analysis. This is followed by a bibliography and seven appendices that augment the analysis presented in the Chapters.

CHAPTER II

DATA SOURCES

Data for the cost analysis (Chapters III and IV) come from two primary sources: (1) results of previous relevant analyses and (2) a sample of approximately 500 PMN chemicals. The previous analyses used for this study are listed in Section A, along with brief annotations of each study's purpose, method, and findings. Section B briefly describes the sample of PMN chemicals used for this analysis.

Data for the innovation analysis in Chapter V come from (1) the cost analysis in Chapter IV, (2) a study commissioned by the Chemical Specialty Manufacturers' Association (Heiden and Pittaway 1981), and (3) previous ICF work for OPTS under Contracts 68-01-5878 and 68-01-6287. The health effects analysis in Chapter VI was based on data from PMN submissions and toxicological literature.

A. RELEVANT PREVIOUS ANALYSES

This section briefly summarizes the nine previous analyses which proved useful in providing relevant data for this study. They are presented in chronological order. Brief discussions of the purpose, method, and findings are provided for each analysis.

1. Impact of TSCA Proposed Premanufacturing Notification Requirements

Prepared by: Arthur D. Little (December 1978)

Prepared for: Office of Planning and Evaluation
U.S. Environmental Protection Agency

Purpose: The purpose of this report (ADL 1978) was to analyze the costs and economic effects associated with a form consistent with the proposed Premanufacturing Notice Requirements of January 10, 1979 (44 FR 2242). The report deals only with the direct out-of-pocket costs of submitting the information and the potential for reducing the number of new chemicals introduced into commerce as a result of these costs. Not included in the analysis were delay costs, confidentiality costs or uncertainty costs, although the possible existence of these costs was recognized.

Method: The report was based on available data on the composition and introduction rate for new chemicals. This included data from patent files, trade industry buyers guides, and interviews with chemical industry personnel. Costs per submission appear to have been based on estimates provided by Arthur D. Little personnel with chemical industry experience.

Findings: Costs of compliance were expected to fall into three ranges: minimum mandatory submission, maximum mandatory submission and maximum total submission. The maximum mandatory submission includes all information required under this option. The minimum mandatory submission excludes some of this information, that may not be required in all cases because of the nature of the new chemical. The maximum total submission includes certain optional information. Costs were expected to vary from firm to firm, depending on size of the firm, characteristics of the new chemical, and availability of data within the firm. Small firms were likely to be affected to a greater extent by the notification requirements due to the inability to take risks that a larger company could more easily absorb.

The average cost of submission was stated to be the maximum mandatory submission. This was estimated to be $3,700 to $42,000 per submission. Based on the ADL estimate of 1,000 new chemicals introduced for commercial sales each year prior to the initiation of the section 5 program, it was estimated that 750 new chemicals would be introduced if the submission costs were $3,700 per chemical, but only 300 new chemicals would be introduced if submission costs were $42,000 per chemical. An important aspect of this analysis was that it assumed companies could not pass submission costs through to customers via higher product prices.

It was observed that the effects of the section 5 rules would vary not only by firm size but also by segment of the chemical industry. The segments most affected were expected to be Soaps and Detergents, Surfactants, and Industrial Organic Chemicals.

2. Estimated Costs for Preparation and Submission of Reproposed Premanufacture Notice Form

Prepared by: Arthur D. Little, Inc. (September 1979)

Prepared for: Office of Toxic Substances
U.S. Environmental Protection Agency

Purpose: The purpose of this report (ADL 1979) was to estimate direct costs of preparation and submission of the EPA79 information requirement. These costs covered only the initial preparation of the PMN, including submission costs and confidentiality costs, and did not consider supplemental reporting costs, delay costs, or uncertainty costs. ADL also estimated costs of the CMA79 information requirement in its comments on the January 1979 EPA proposal.

Method: The analysis was based on discussions with EPA staff on the nature of the information requirement and instructions. Chemical marketing, chemical and environmental engineering, chemistry, data analysis, and toxicology considerations were examined by ADL staff experts in order to establish a system that would enable estimates to be made regarding time to prepare the submission. Interviews with chemical companies were carried out to verify ADL findings on direct costs. These interviews lent additional credence to the original cost estimates.

Findings: The cost of complying with the EPA79 Premanufacturing Notice was estimated to be in the range of \$2,055-\$15,325 per chemical, including confidentiality costs. The submission costs alone were estimated to be in the range of \$1,155-\$8,925, and confidentiality costs were estimated to be \$900-\$6,400. The range in cost was attributable to differing amounts of time and professional expertise required to provide the information. These in turn depended on the nature of the chemical, the amount of data that could be easily collected, and company specific factors such as in-house research capability.

ADL supplied cost estimates for the CMA79 (Chemical Manufacturers Association) alternative information requirement. For the mandatory sections, the cost was estimated to be from \$955 to \$5,500.

No new estimates for the number of new chemicals requiring PMN submissions were presented.

3. Economic Analysis of Proposed Section 5 Notice Requirements

Prepared by: ICF Incorporated (September 1980)

Prepared for: U.S. Environmental Protection Agency

Purpose: The purpose of this report (ICF 1980) was to examine the costs of several regulatory alternatives for implementing section 5. ICF examined the costs of preparing section 5 notices under three different program alternatives. Costs identified included out-of-pocket costs, delay costs, and uncertainty costs associated with the ultimate disposition of the section 5 submission. Economic effects on the chemical industry were examined as were economic effects on the economy as a whole.

Method: First a baseline of the chemical industry was created, based on the economic behavior of important chemical industry segments in the absence of section 5 rules. Next, the types of costs imposed by section 5 were identified and quantified as much as possible, based on data available at that time. Section 5 rules were expected to produce the following types of costs: direct out-of-pocket costs associated with completing reporting requirements, costs associated with the delay in the introduction of new chemicals, uncertainty regarding possible additional out-of-pocket costs and/or delay costs, possible trade secret disclosure, and costs associated with possible restrictive action by EPA. Although only the direct out-of-pocket costs could be quantified based on data available at that time, the other costs were expected to dominate the out-of-pocket costs.

The costs due to these factors were examined on four levels: individual chemicals, individual companies, industry segments, and the U.S. economy as a whole. Estimates were quantified wherever possible, but the less direct the economic effect, the more difficult it was to achieve meaningful quantification.

The segments of the chemical industry most likely to be affected by the notice requirements were catalysts, surfactants, cyclic intermediates, rubber processing chemicals, plasticizers, synthetic organic chemicals, adhesives and sealants, industrial inorganic chemicals, and plastics and resins. The economic impact of the notice requirements was said to depend more on EPA's use of the information provided than on the administrative costs of reviewing submissions. Smaller companies could suffer more because of the notice requirements since they were expected to have fewer resources to divert to non-production activities. Small companies that produce low volume chemicals could face higher direct costs relative to the profit generated.

Another likely effect of these regulations was noted to be a reduction in new chemicals introduced into the market. Companies might also shift innovation over to "safer" areas of chemical innovation. (By "safer", ICF, in 1980, meant chemicals with lower toxicity and lower exposure. Another aspect of "safer" noted by the CSMA in 1981 is the shift to greater emphasis on development of chemicals at customer request rather than for the general market).

The out-of-pocket costs per submission were estimated by ICF to be as follows:

minimum guidance:[3]	\$1,000 - \$7,500
EPA79(Oct. 16, 1979)	\$1,200 - \$8,900
EPA proposal (Jan. 10, 1979)	\$3,700 - \$42,000

Associated with all three options is the cost of claiming confidentiality of \$900 - \$6,400. Other costs such as delay and uncertainty could not be quantified but were expected to exceed the out-of-pocket costs.

4. Pre-Manufacture Notification Under the Toxic Substances Control Act

Prepared by: Council on Wage and Price Stability, March 13, 1981

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[3] This was a set of information requirements which in mid-1980 the Agency considered to be the minimum statutorily allowed.

Prepared for: Office of Pesticides and Toxic Substances
U.S. Environmental Protection Agency

Purpose: The purpose of this report (CWPS 1981) was to bring to the attention of EPA the possibility that the Premanufacture Notice program might have significant detrimental impacts on innovation and productivity in the chemical industry. The effect of cumulative regulatory burden was examined in order to get an idea of the cost over time, since immediate effects would not be as noticeable. This is because the success of a new chemical may not be realized until several years after it has been on the market. CWPS also expressed concern that not enough work had been done to assess the benefits of section 5 rules.

Findings: This document was a critique of the PMN program as of December, 1980. Special attention was given to cost effectiveness, because CWPS felt this aspect of toxic chemical regulation had never been sufficiently addressed. CWPS felt that benefits should be examined in parallel with the analysis of chemical risks in order to justify the regulatory impact on innovation. Although CWPS recognized the difficulty in quantifying health and environmental effects attributable to the section 5 program, concern was nevertheless expressed that benefits should be quantified to the maximum extent possible.

Regarding costs, no criticisms were made of the estimates of direct filing costs. However, delay and uncertainty costs were seen to be major costs far outweighing the costs associated with submission of the PMN form. An important economic effect mentioned was the potential for reduced innovation due to higher costs of successfully developing a new chemical.

CWPS suggested that EPA examine a broader range of alternatives for reducing the environmental and health hazards associated with all chemicals.

The possibility of a shift in priorities was raised, from regulating new chemicals, to regulating hazards of existing chemicals. CWPS strongly recommended that EPA evaluate the mix of controls over new and existing chemicals. It was suggested that EPA consider whether it might be more cost-effective to give greater attention to regulating existing chemical hazards rather than promulgating more stringent regulations for new chemicals.

5. Cost Estimation of the Section 5 Notification Form Proposed by the Chemical Manufacturers Association

Prepared by: ICF Incorporated (July 1981)

Prepared for: U.S. Environmental Protection Agency

Purpose: The purpose of this analysis (ICF 1981) was to estimate the direct costs of submission for the alternative PMN form proposed by the Chemical Manufacturers Association.

Method: ICF used the well-established costing method of estimating labor requirements and applying labor rates to determine submission costs.

Findings: The CMA79 information requirement has two parts, a mandatory portion and an optional portion. It was determined that the CMA79 requirement would have cost $1,250 - $5,930 for the mandatory portion, and $0 - $13,859 for the optional portion, for a total cost of $1,250 - $19,789. These costs are summarized below:

	Mandatory	Optional	Total Cost
CMA	$1,250 - $5,930	$0 - $13,859	$1,250 - $19,879

6. The Impact of TSCA Regulations on the Chemical Industry: A Pilot Survey

Prepared by: National Economic Research Associates, Inc. (NERA)
(January 20, 1981)

Prepared for: The Chemical Manufacturers Association

Purpose: The purpose of this study (NERA 1981) was to determine the feasibility of using a survey method to evaluate the direct cost of TSCA regulations as they evolve and to develop data and an analytic framework for determining direct and indirect economic effects of future proposed regulations.

Method: NERA developed an industry survey with two objectives in mind. The first objective was to ascertain the costs to industry of TSCA regulations. The second objective was to develop a model that could evaluate economic effects of interim regulations. These costs are based on data for a sample of 36 firms representing 14.7% of total domestic chemical sales.

Findings: For the period 1977-1979, total direct TSCA costs were estimated to be about $300 million. These included not only costs of section 5, but also any costs related to testing rules, PCB disposal and recycling, section 8(a) inventory reporting, and reporting imminent hazards. About 25 percent of these costs were for health and environmental testing of new chemicals. Another 25 percent was for submission costs, 17 percent for increased product review, and the remaining 33 percent was for legal review and costs of following legislative and regulatory activities. TSCA-related expenditures, directed toward increasing the health, safety, and environmental quality of chemials in commerce, totaled $1.1 billion. About $800 million of this was for health and environmental testing. $700 million of these costs would have occurred even without TSCA.

With respect to new chemical substances, NERA estimated that 1,700 new chemicals are introduced annually (the 90 percent confidence interval was 450-3000). Other NERA findings about new chemicals included: a new chemical takes an average of three years to develop, has a 40.3 percent chance of successful commercialization, incurs average research costs of $225,900, and earns an average pre-tax rate of return of 37.8 percent.

7. A Critique of the EPA "Economic Impact Analysis of Proposed Section 5 Notice Requirements"

Prepared by: Regulatory Research Service (RRS), (March 1981)

Prepared for: Chemical Manufacturers Association

Purpose: The purpose of this critique (CMA 1981) was to review the ICF analysis of the proposed section 5 notice requirements under TSCA and to provide additional data on costs of section 5 rules.

Method: The RRS critique deals with two major areas of the ICF analysis: (1) cost analysis of the PMN process; and (2) evaluation of effects, especially on innovation. Additional information was provided based on a sample of PMN chemicals and a survey of 37 CMA member firms.

Findings:

- Cost Issues--RRS stated that ICF had not adequately covered some cost categories. These included uncertainty costs, overhead costs, costs of PMNs required for intermediates that never see commercialization, and economic costs of submitting PMNs for developmental chemicals that will be commercialized later. Other costs would include PMNs for commercial failures and general uncertainty costs. Based on data from the industry survey and the sample of PMNs, these costs were estimated as follows:

  Average filing costs were $7,548 per PMN filed, and a figure of $4,500 was estimated for additional costs. Thus a cost estimate of $12,000 per PMN submission was given as the total cost of PMN per new chemical.

- Impact Analysis--In the executive summary, RRS stated that innovation had declined between 70 and 90 percent as a result of the PMN process. The analysis simply compared earlier estimates of the number of new introductions with the number of PMNs being commercialized. After removing PMNs on intermediates and PMNs on developmental materials from the 470 PMNs reviewed by RRS only 294 are "valid." This number was compared to previous estimates (2220 from the Snell report, 1700 from NERA, and 1000 from ADL). Innovation decline was presumed to be wholly attributable to the cost of PMN filing, including delay and uncertainty costs.

8. Impact of the Toxic Substances Control Act on Innovation in the Chemical Specialties Manufacturing Industry

Prepared by: Regulatory Research Service (January 1982)

Prepared for: Chemical Specialties Manufacturers Association (CSMA)

Purpose: The purpose of this analysis (Heiden & Pittaway 1982) was to determine the impact to date of TSCA on innovation in chemical specialties manufacturing and to define the nature of such impact. A second objective was to create a baseline that could track the effect of TSCA on innovation over time.

Method: The approach used to collect data for this analysis was a mail survey combined with a series of interviews with representatives from a sample of member CSMA firms. The study was limited to the 198 member firms who were identified as either ingredient suppliers or product manufacturers. Mail questionnaires were sent to all members (69/198 responded) that fit the description of ingredient suppliers or product manufacturers. The complete study consisted of 100 firms, 50 that responded to the questionnaire, 19 that responded to the questionnaire and had field interviews, and 31 that had only field interviews.

The survey was designed to collect three kinds of data: (1) economic background; (2) new product development five years prior to and after TSCA PMN implementation; and (3) decisions made to undertake or reject innovation.

Findings: This analysis reported that innovation appears to have declined since 1979 for ingredient suppliers. This was the first year of implementation of TSCA pre-manufacturing notice requirements, although decline due to TSCA couldn't be totally separated out from other causes.

Small business firms were noted to have much greater dependence for continued sales on new product innovation. There was a 38% reduction in the relatively risky area of general market innovation, and only a 14% reduction in innovation in the less risky area of customer requests.

Product manufacturers had not yet experienced any reduction in innovation, possibly because the effect in this area would be due to the significant new use rules which had not been proposed at the time the analysis was conducted (1981). Thus, for product manufacturers, the innovation data can be considered as a baseline against which future TSCA effects can be measured.

When added to direct filing costs, non-requirement induced actions such as health and safety testing become substantial costs which, when balanced against the expected return from new substance reduces the incentive to innovate. Because these costs are fixed, they are particularly burdensome to small firms, i.e., those below $200 million in annual sales.

9. Economic Impact Analyses of TSCA Section 5(h)(4) Exemptions: Low Volume, Site-Limited Intermediates, and Polymers

Prepared by: Regulatory Impacts Branch
Economics and Technology Division (March - May 1982)

Prepared for: Office of Pesticides and Toxic Substances
U.S. Environmental Protection Agency

Purpose: The purpose of these reports (Ng 1982, Warhit 1982, Luttner 1982) was to determine the extent of relief that would be provided by EPA's proposed exemptions for certain low volume chemicals, site-limited intermediates, and polymers. Three exemption analyses were developed: low volume chemicals (Ng 1982), site-limited intermediates (Warhit 1982), and polymers (Luttner 1982). Under section 5(h)(4) of TSCA, new chemicals may be exempted by rule from the reporting requirements of section 5 if the substance is determined to present no unreasonable risk of injury to health or the environment. EPA has proposed to exempt certain new chemicals if production does not exceed 10,000 kg per year, certain new site-limited intermediates manufactured in any quantity, and polymers that meet certain EPA requirements. (Details of EPA's proposed exemptions are presented in Section IV F of this report.) Each of the economic analyses considered several options, and the proposed exemptions were based on those options that appeared to meet regulatory objectives for the least burden.

Method: In the economic analyses, exemption options were evaluated using a sample of about 500 PMNs. Thus, chemicals and firms which might be affected under the alternative exemption options were characterized. Firms were assumed to incur several types of costs: direct filing costs, confidentiality costs, delay costs, and uncertainty costs. These costs reduce the expected rate of return on a new chemical and increase the economic risk to a firm.

Exemption options were presented and economic analyses were undertaken to evaluate the savings to EPA and to industry.

Findings: After considering all of the alternatives for each of the three types of exemptions, the following exemptions were proposed (these are explained in detail in Section IV F):

- Low Volume: Chemicals with annual production volume (or import volume) less than or equal to 10,000 kg are potentially eligible for exemption. EPA would review exemption requests within 14 days and may refuse to grant an exemption.
- Site-Limited Intermediates: The site-limited intermediate exemption is similar to the low volume exemption. Manufacturers must submit an exemption notification and a qualified expert, employed by the manufacturer, must review the chemical. EPA has 14 days to act on exemption requests.
- Polymers: The polymer exemption is much more complex than the other two exemptions and involves fulfilling certain technical criteria. If all of the criteria are met and the polymer has a number average molecular weight over 1,000 g then the polymer would be eligible for a 14 day notice.

  A polymer would be eligible for a zero day exemption notice (exempt from all PMN requirements) if it met one or more of the following requirements:

  1) Polyesters made from a specified list of monomers.
  2) Polymers with number average molecular weight of 20,000 or greater.
  3) Polymers with certain number average molecular weight and polydispersity values.

- Chemicals Used in or for the Manufacture or Processing of Instant Photographic or Peel-apart Film Articles: EPA exempts manufacturers of instant photographic and peel-apart film articles who manufacture and process new chemical substances used in or for the manufacture or processing of these articles from the premanufacture notice requirements of TSCA section 5. Under same circumstances the companies may manufacture and process a new chemical substance for use in or for these articles immediately upon submission of an exemption notice. Distribution in commerce of the photographic articles is not permitted until the manufacturer complies with the premanufacture notification requirements of TSCA section 5(a)(1)(A) and the review period has ended without EPA taking any action to prevent distribution or use.

Cost Savings: The cost savings for the proposed low volume exemption were estimated to be from \$195,000 to \$1,802,000 for the chemical industry or \$700 - \$6,000 for each exemption notice. EPA cost savings were estimated to be \$802,000 or \$3,000 for each exemption notice (Ng 1982, p. xi).

The cost savings for the proposed site-limited intermediate exemption were estimated to be from \$35,000 to \$370,000 for the industry or from \$400 to \$7,050 for each exemption notice. EPA cost savings were estimated to be \$148,000 or \$2,800 for each exemption notice (Warhit 1982, p. vii and x).

The cost savings for the proposed polymer exemption were estimated to be from \$190,000 to \$1,410,000 for the industry or from \$500 to \$3,700 for each exemption notice. EPA cost savings were estimated to be \$410,000 (Luttner 1982, p. vii).

These estimates of savings were based on the number of new chemicals annually qualifying for the various types of exemptions. For each eligible chemical, savings were calculated based on the expected direct cost of filing a PMN under the EPA79 less the cost of filing the least costly exemption application for which the chemical was eligible.

10. Summary of Previous Analyses

These nine studies were utilized in developing the analyses presented in this report. In addition, comments received by EPA in response to previous section 5 regulatory proposals were utilized as general background. The other major data source was a sample of approximately 500 PMNs. This sample is described below in section B.

B. DESCRIPTION OF THE PMN SAMPLE

In order to estimate important parameters needed for this analysis, a sample of approximately 500 PMNs was selected. This sample was drawn from a time interval representative of a steady state of PMN submission and had the following characteristics:

- 19% of the sample chemicals were intermediates
    - 10% were site-limited intermediates
    - 9% were others
- 42% had annual first-year maximum production volume of 10,000 kg or less
    - 20% had first-year production volume <1,000 kg
    - 22% had first year production volume between 1,000 and 10,000 kg
- 49% of the sample were polymers
- 10% of the sample were used in photographic applications
- 64% of the sample qualified for some type of exemption (based on the exemption alternatives presented in Chapter IV)

- 6% needed additional information or were subject to some type of restriction (e.g., regulation by 5(e) or 5(f), request to change a label, a reformulation or a change of process) or were voluntarily acted on by the companies.

Other characteristics of the sample are presented in Chapter IV, as they need to be introduced.

CHAPTER III

IDENTIFICATION AND ANALYSIS OF PRIMARY ECONOMIC EFFECTS ASSOCIATED WITH THE PMN PROCESS

This chapter reviews relevant portions of previous studies of the costs of the section 5 notification program, identifies which costs contribute to the primary economic effects discussed in Chapter II, and explains the data and techniques used in Chapter IV to compute costs. Section A reviews and contrasts the "costs" identified in previous studies concluding that four measurable costs contribute directly to the effect. Sections B through E discuss each of these four cost components.

A. SCOPE

Analyses of the costs incurred by chemical firms to fulfill PMN requirements have been made by several organizations, including two EPA contractors (Arthur D. Little, Inc. and ICF Incorporated) and a Chemical Manufacturers Association (CMA) contractor (Regulatory Research Service). These analyses included evaluations of the original PMN form proposed by EPA (published in January 1979), the "reproposal," published in October 1979, a set of information points required under a minimum guidance scheme which did not include a form (this scheme was derived by ICF as an optional reporting system in its October 1980 report), and a form proposed by the Chemical Manufacturers Association (this was also analyzed by ICF and ADL).

The estimates developed in the several PMN reporting cost analyses varied widely due to three major factors: 1) differences with respect to assumed data requirements; 2) differences with respect to the types of costs associated with the PMN process; and 3) differences in assumed unit costs for the various types of costs.

All of the analyses recognized the direct out-of-pocket costs associated with the PMN process, i.e., "direct filing costs." ICF, ADL, and RRS also attempted to evaluate confidentiality assertion and substantiation costs. ICF analyzed two other categories of costs: 1) delay costs, and 2) uncertainty costs. The Regulatory Research Service (CMA 1981, p. XV) analysis concurred with ICF's statement of cost types and concluded that four additional cost factors must be included in an analysis of PMN cost impacts. These were: 1) non-trade materials costs (PMNs filed on materials not produced for direct sale or trade); 2) developmental materials economic costs (PMNs filed on materials which do not become successful commercially); 3) cost of testing conducted due to an implied or perceived "need"; and 4) a miscellaneous category of non-labor direct costs which includes, among others, the post-submission costs of communications. Of the many costs derived above, ICF believes that only direct filing costs, delay costs, confidentiality costs, and costs due to actions required by EPA during its review of the PMN should be measured. In the following paragraphs, the reasons for dismissing the other costs are presented.

1. Non-trade Materials

We have not examined the marginal costs of submitting PMNs on non-trade materials (intermediates used to produce other chemicals) because analysis of the PMN data base indicated that the costs of filing the additional PMNs for intermediates to a final product PMN are very low exclusive of additional health and safety testing (which is not, of course, specifically required by the statute). ICF reviewed a random sample of about twenty end-product PMNs that had approximately 50 intermediates associated with them to determine the extent of changes between the end-product and the intermediate PMNs. The only two information items to change significantly among the intermediates and the end-product were the chemical identity and health and safety data. In the vast majority of PMNs examined, there was the possibility that the company had performed separate health and safety tests on each PMN chemical; however, this majority is deceiving in that it is due to the distortion caused by a single company (which accounts for 2/3 of all intermediates in the sample). This company appears to perform this testing routinely in its new chemical development process.

When the information supplied about the final product and the intermediates is compared, strikingly similar information appears in many places. Exposure-at-the-manufacturer's-sites, manufacturers-identity, and exposure-at-others'-sites (when supplied) changed very little. For example, information about exposures at manufacturers' sites often were the same among intermediates and final products except for number of workers exposed. The cost of supplying this incremental information is not large enough to warrant analysis.

The only item that consistently differred was chemical identity. Thus, the marginal cost of an intermediate PMN generally was the cost to provide chemical identity and the cost of typing the form. As explained in Chapter IV, Section B, the cost of providing chemical identity information is two technical hours and the cost of typing the form is 5 clerical hours for an incremental cost of $188. This estimate is much less than the $2,279 estimate based on the assumption that the intermediates require a completely independent PMN submission (CMA 1981, p. III-55).

2. Testing Costs

Testing of new chemicals is not required as part of the Premanufacture Notification process under section 5 of the Toxic Substances Control Act. The only references to testing in section 5 are section 5(d)(1) and section 5(b)(1)(A). Section 5(b)(1)(A) states that a manufacturer of a new chemical subject to a section 4 test rule must submit the test data specified in the rule as part of the premanufacture notice required under section 5. At this time, EPA is exploring ways to apply section 4 test rules to categories of chemical substances as authorized by section 26(c). Once category test rules are in effect, a new chemical substance which is a member of a defined category will be subject to the testing requirements as provided by section 5(b)(1)(A). The EPA has recently proposed test rules affecting categories of chemicals. However, none of these test rules is final yet.

Section 5(d)(1) requires the submission of test data in the possession or control of the person submitting the notice which are related to the effects on health or the environment from the manufacturing, processing, distribution in commerce, use, and disposal of the new chemical substance. This section does not require testing but if tests have been performed the results must be submitted.

In previous analyses of the cost of the section 5 premanufacture notification program only the costs of reporting the results of tests have been analyzed. These costs, between $300-$1,700, have been included in the costs of filing PMNs (ADL 1979). An additional cost element which has not been utilized in this filing cost analysis, is the cost of the tests themselves.

CMA and other affected parties have argued that although the law is clear that testing is not required, many companies are performing tests they would not otherwise perform, because they believe the Agency will find fault with their premanufacture notice if test data are not submitted. Therefore, CMA argues that the costs of testing should be included in the cost of the program. Although the costs of such testing cannot be counted as a direct component of the PMN impact (since testing is not required by TSCA), such costs could be important induced effects of the section 5 rules; particularly given that many ingredient suppliers surveyed by CSMA view PMNs as requiring incremental testing costs, sometimes in significant amounts (CMA 1981). In Chapter IV, we discuss testing costs in the context of actions undertaken at EPA's request. The cost of tests are analyzed for those cases where, during the PMN process, EPA recommended testing as a source of additional data to aid their evaluation of risks.

3. Uncertainty

Uncertainty concerning the PMN process takes many forms. In previous analyses (ICF 1980, Heiden and Pitaway 1982) the kinds of uncertainty factors addressed included:

- uncertainty regarding the length of delay
- uncertainty regarding total direct costs of filing
- possible trade secret disclosure
- possible regulatory or voluntary restrictive actions

None of these factors were quantified in previous analyses because no data existed to evaluate them. Because the program has been in place for three years and a track record exists regarding length of delay, trade secret disclosure, and restrictive actions, it is possible to compute a minimum estimate of the cost of these uncertainties.

The manifestation of these uncertainties is the record of the Agency in implementing the section 5 program. For example, if EPA has revealed trade secrets then the extent of damage due to trade secret disclosure can be used as a proxy for the degree of uncertainty faced by manufacturers. Likewise, EPA's use of extension authority to extend the ninety day period is a measure of the extent of the length of delay uncertainty. Additionally, based on conversations with EPA staff and review of the telephone records of over 700 PMNs in EPA files, it appears that EPA's practice of orally requesting additional information on a regular basis may be a measure of the uncertainty associated with direct filing costs. Finally, uncertainty regarding possible restrictive actions is directly measurable by the frequency and magnitude of cost imposed by EPA when it has taken specific action on a chemical. Because uncertainty manifests itself this way, it can be measured within the context of direct filing costs, costs of protecting confidential business information, and cost of delay.

4. Developmental Materials

In (CMA 1981) Heiden and Pittaway identified the cost of submitting PMNs on developmental materials as an additional cost to be computed. They noted that this cost was a behavioral response (CMA 1981, p. III-55) not a requirement of the program. As mentioned above, this analysis considers the direct costs of the regulation not the induced costs. Therefore, the costs of PMNs for developmental materials is not of concern here. Indirectly we do address this cost, however, because we estimate the annual costs of the program without removing developmental materials. That is, we assumed that some portion of the PMNs that are not commercialized are developmental materials.

5. Summary

The ability to dismiss non-trade materials costs, to measure testing costs through explicit EPA requests, and to measure uncertainty through actual experience with the program reduces the cost categories to be analyzed to four:

- direct filing costs,
- delay costs,
- confidentiality costs, and
- expected costs of EPA-induced restrictions (labels, tests, withdrawals).

The approaches to computing the costs of each category are presented in Chapter III, Sections B through E.

B. DIRECT FILING COSTS

As previously stated, the actual out-of-pocket costs incurred by firms to collect the necessary data, complete a PMN form, and file it with EPA have been the subject of several analyses. The seven costs estimates prepared to date are presented in Exhibit III-1 below.

EXHIBIT III-1

ESTIMATES OF DIRECT PMN FILING COSTS
(Dollars)

Estimate Source	Basis	Estimated Cost Per PMN
ADL (1978, p. V-17)	January 1979 proposal	\$3,700 - \$42,000
ADL (1979, p. 38)	EPA79 form	\$1,200 - \$8,900
ADL (1979, p. 64)*	CMA79 form	\$995 - \$5,550
ICF (1980, p. A-25)	Minimum Guidance Scheme	\$1,000 - \$7,900
CMA (1981c, p. viii, x)**	Critique of ICF Analysis	\$6,375
ICF (1981, p.4)***	CMA79 form	\$1,110 - \$5,320
ICF (1981, Dresser Memo)	Actual Data Supplied on PMNs	\$1,200 - \$7,900

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*Mandatory portion only. Optional portions may cost from \$0 to \$11,500.

**Mean total filing costs less confidentiality costs, including cost of PMNs on chemicals that are not commercially successful.

***Mandatory portion only. An optional portion may cost from \$0 to \$12,490.

A possible source of inaccuracy in the first few estimates prepared for EPA is that they assumed PMN submitters would complete certain portions of given forms or would be required to provide certain data. Most of the estimates were therefore predictive rather than being based on analysis of PMNs actually submitted to EPA by firms. RRS obtained their estimates by asking firms in their survey what their costs had been for submitting PMNs and found their pre-submission filing costs to be $5,427 (labor costs of $4,270 and overhead charges of $1,157). By adjusting for chemicals unsuccessful in customer testing they raised this estimate to $6,375.

In order to produce a more accurate estimate of actual pre-submission PMN costs, ICF conducted an analysis of the cost of PMN submission based on actual data received in a sample of about 500 PMN submissions received during 1980 and 1981. The analysis identified which pieces of information in the EPA79 form were provided by PMN submitters. Form sections were considered complete if one item in the section was supplied. The estimated hours needed to complete each section for which information was supplied were summed and multiplied by the appropriate labor rates and/or other inputs needed to complete the submission. The cost estimates contain an upward bias to the extent that form sections were considered complete even if only one item was provided within the section. However, this must be offset against a downward bias because some submitters provide data not requested in the EPA79 form and because the data base did not gather information about transport or consumer use/exposure. This analysis concluded that the net impact of these factors was an upward bias in the cost of completing the forms. Overall the average cost of the typical PMN, based on actual PMN submissions in the data base, ranged from about $1,200 to $7,900, assuming October 1980 labor rates.

In the remainder of this section, approaches for estimating labor hours are provided in section 1, while costs for required labor are discussed in section 2 below.

1. Labor Hours Estimates

All cost estimates to complete the PMN have depended on two critical factors--labor hours required and costs of labor. The amount of labor hours required depends on three factors:

- the amount and type of information to be submitted,
- the efficiency at which employees fill out requested information,
- characteristics of the firm.

a. Amount and Type of Information

The amount and type of information requested by a form and likely to be completed by a firm varies a great deal depending on: properties of the new chemical substance, characteristics of the manufacturer, and the manufacturer's production plans. Some examples of this variability follow:

> Example 1. Suppose that a form has a separate section for which information is to be supplied only with regard to production of the new chemical at sites not controlled by the submitter.[4] If the submitter expects to be the only producer of the new chemical, then no information would be supplied for this section. On the other hand, if the submitter expects other firms to also produce the new chemical, it may have a great deal of information to provide. In the first instance virtually no labor would be necessary, while in the second instance a substantial amount of labor could be required.

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[4] "Submitter" refers to the firm that is submitting the section 5 notice.

Example 2. A section 5 notification form is likely to request information on worker exposure to the new chemical. If the new chemical is manufactured in a completely enclosed system, there may be virtually no worker exposure, and the manufacturer would have little to report. However, a different manufacturing process could expose several employees in several different situations. In this case the submitter would provide a great deal of information. This problem would be compounded in those cases where the submitter had not finalized its production process; i.e., when the optimal system could be identified only after production of the substance in commercial quantities had begun.

Example 3. A form might request the submitter to provide any analyses that the firm performed of the possible health and environmental risks of the new chemical substance. Therefore, if the firm conducted such analyses it would submit them as part of the information requested in the form. If no such analyses were conducted, the firm would have nothing to submit.

b. Efficiency of Labor

The time required for a person to perform a duty varies depending on that person's efficiency. Learning curve effects should reduce hour requirements for any given firm after the first few PMNs are submitted, thereby resulting in costs closer to the low end of range estimates provided in previous analyses. Although this point may seem obvious, failure to take into account learning curve effects may cause ICF's (and ADL's) estimates of labor requirements to be higher than actual requirements in the long-run.

c. Characteristics of the Firm

The labor needed to provide information may vary considerably based on the size, resources and organization of the firm. For example:

Example 1. If a firm is small, then a top-level manager could also be a chemist who is familiar with the technical aspects of the manufacturing process. As a result, he or she might fill out the technical information requested by the form. Thus, smaller firms are more inclined to use higher level personnel to fill out information (ADL 1979, p. 14).

Example 2. The firm may as normal practice conduct risk assessments. Suppose an industrial hygienist conducted an analysis of the health risks that may result from occupational exposure to the new chemical, and that after this analysis was performed the firm then begins to complete a section 5 notice. In this case, much information on occupational exposure would be available for submission. On the other hand, if the firm did not conduct risk assessments routinely, such an analysis would not be conducted, and so the firm would have less information to provide on occupational exposure.

Example 3. More than one branch of the firm may be involved in submitting the section 5 notice, e.g., a research and development branch may provide data on chemical properties, a marketing or planning branch may supply production information, a government-regulations branch may manage the submission, etc. Suppose the management of the firm is organized in a relatively hierarchical structure. In this situation, when different branches coordinate efforts to submit the form there may be a minimum of confusion. If the branches are more autonomous, however, there may be more coordination required. The more coordination required, the more labor will be required to fill out the form (ADL 1979, p. 12-13).

2. Summary

Because of these factors--amount and types of information, efficiency of labor, and characteristics of the firm--required labor for a particular form may vary considerably among different companies and different chemicals. Thus, range estimates are needed to account for the variability of these requirements. Our approach consisted of the following steps:

1. Estimate labor hours for each of the general categories of labor: clerical, technical, and managerial (ADL 1978, p. V-9 to V-15);
2. Estimate the maximum and minimum possible hours to compute a range of hours (e.g, 5-10 technical hours) for each of these categories; and
3. Multiply these hour estimates by average industry labor cost per hour for each category.

Hour input estimates vary by reporting rule alternative, while cost per hour does not. In Appendix A, per-hour labor costs (as of December 1981) are estimated. Hour input requirements are developed in Chapter IV, Section B.

C. DIRECT COST OF DELAY

In this section the direct costs of delay are explained. Section 1 presents the two components of direct delay costs: pre-submission delay and post-submission delay. Section 2 presents a general approach for valuing both of these delay components.

1. Components of Direct Delay Costs

For this analysis the primary cost of delay is defined as the present value of profits delayed because of the PMN process. Delay costs are specified in profits rather than sales because while PMN imposes delays in revenue streams, it also imposes delays in cost streams. Therefore, the loss due to delay should consider revenues net of costs--i.e., profits.

Primary delay costs here are defined as the net present value of the profit stream before and after delay, not profits foregone. This is an important distinction. Although PMN delay may contribute to new chemicals losing sales to existing products, thereby resulting in profits foregone, such losses are secondary effects of PMN. The primary effect of PMN is, in some instances, to delay for three-months the introduction and thus reduce the value of a certain amount of profit. Since the value of profit is greater today than three months from now, the decreased present value of the profit stream represents the primary delay cost of PMN. To be sure, it is conceivable that there may rarely be seasonal or single-batch chemicals for which demand is immediate and where the 90 day-delay alone prohibited the chemical from being marketed. But these are secondary effects that result from delay (and generally insignificant costs in the scheme of the total production of the chemical industry), not the primary effect of delay. (In this part of the RIA we are measuring primary effects.)

Thus, the definition of primary delay costs as a reduction in the present value of the profit stream is operative here. Delay costs can be broken into two components: pre-submission delay and post-submission delay. Pre-submission delay would include the amount of time it takes a firm to compile and submit a section 5 notice. At the present time, based on data from a sample of 37 CMA member firms, a maximum estimate for the pre-submission delay interval would be one month (CMA 1981, p. III-37). Such delay would not include any time for the completion of testing. However, because section 5 does not require submitters to perform health and safety testing, any delay due to testing prior to submission of a PMN would not be attributable to the PMN process. If submitters feel they need to develop additional health and safety data before submitting a section 5 notice (for whatever reason) they do so voluntarily. Therefore, costs attributable to delay due to voluntary increased testing should not be considered direct costs of the PMN program.

Post-submission delay would correspond to time lost due to the PMN review period -- a maximum of 180 days (assuming the maximum 5(c) extension).

For both components, the delay period is defined as the time which the review period adds to the critical path for bringing a new chemical to market. If the PMN review can be conducted in parallel with other activities along the critical path (in-house development, customer evaluation, etc.), delay is zero. If no part of the preparation of the PMN or EPA review of the PMN can be conducted in parallel with other critical path activities, the cost of delay will approach the present value of delaying the profit stream by 120 days (the sum of the pre- and post-submission periods) if no 5(c) extension is filed).

A worst-case scenario would assume PMN review always adds at least 90 days to the critical path. It is possible that the delay period could exceed 90 days depending upon the extent to which section 5(c) actions are pursued, thereby extending the review period for up to an additional 90 days. Since October 1, 1980, 11 5(c) actions have been taken. This represents .8 percent of PMNs filed to date. For purposes of this analysis, maximum delay will be assumed to be 120 days for 99.2 percent of all PMNs and 210 days (120 days plus an additional 90 days resulting from 5(c) actions) for .8 percent of PMNs. In essence, the worst-case scenario assumes that PMN review can never be conducted in parallel with other activities along the critical path.

At the other extreme, a best-case scenario of the delay period can be developed by assuming that all activities can be conducted in parallel with other activities along the critical path to the maximum extent possible. In this case, the company plans its PMN submission timing so that the normal 90-day review period expires before or at the same time it wishes to commence marketing the chemical. Thus no days are added to the critical path, except for the very small number of PMNs (0.8%) subject to a section 5(c) action..

CMA (1981) in its critique of previous economic analyses argued that the delay imposed on larger projects of which the new chemical was a part should also be computed as a direct cost of the PMN program. We do not believe that this is correct. First of all, the larger and more complicated the project, the less likely that PMN review will add to the critical path. Second, if there are delays in larger projects due to PMN review, they would most likely occur only in the transitional period as the firm first implements PMN procedures. As industry becomes more familiar with the requirements of PMN, section 5 reviews can be integrated into on-going practice, thereby minimizing the probability that PMN will contribute to the delay of larger projects.

2. Valuation of Delay

As specified in section 1, direct costs of PMN delays are defined as a reduction in the present value of the profit streams associated with new chemicals. Algebraically, such a reduction would be computed as follows:

$$PD = \left[1 - \frac{1}{(1+r)^{t}} \right] \bullet PV(p)$$

where

PD = present value of profits delayed due to PMN delay

t = amount of time (probably in months) attributable to PMN delay

r = average real rate of return (specified in the same time units as t) for new chemicals

PV(p) = present value (discounted at r) of profit stream associated with the average new chemical.

This formula represents the difference between the present value of the profit stream associated with the average new chemical and the present value of the same profit stream lagged "t" time periods. Appendix B contains the derivation of this formula.

To develop an appreciation of the maximum direct delay cost imposed by PMN, consider the above formula when t is 7 months (1 month for pre-submission delay and 6 months for post-submission delay). Assuming that the maximum real rate of return for new chemicals would be 10% annually (or approximately 0.83% monthly), the formula above reduces to the following:

$$\text{Percent profit lost} = 1 - \frac{1}{(1.0083)^7} = 5.6\%$$

Thus, when the real rate of return is 10% annually, the cost of delaying the profit stream seven months exceeds 5% of the present value of the original profit stream for the new chemical. Exhibit III-2 provides some sample calculations for percent of the present value of the profit stream lost for other values of time delay and real rate of return.

EXHIBIT III-2

SAMPLE VALUES OF REDUCTIONS IN PRESENT VALUE
(expressed as percent of profits)

Time Delay Due to PMNs on New Chemicals	Annual Real Rate of Return	
	5%	10%
1 month	0.4%	0.8%
2 months	0.8%	1.6%
3 months	1.2%	2.4%
4 months	1.6%	3.2%

It should be remembered that the above estimates provide an upper bound for the delay costs. Real rates of return may be less than 10% and the time lag due to section 5 delays is usually less than seven months. Quantification of delay effects under the three regulatory alternatives is provided in Chapter IV. Chapter IV also contains estimates of the present value of the profit streams associated with the average new chemical when reasonable assumptions about the discount rate, chemical life cycle, and stream of profits are made. In Chapter IV we also compute a best guess estimate of delay costs based on commencement of manufacture notices received to date.

D. CONFIDENTIALITY

This section presents methods for estimating the relative costs to regulated parties and to EPA of options for the confidential treatment of section 5 notice information. Section 1 outlines the factors that affect confidentiality costs. Section 2 discusses the type of confidentiality costs incurred by regulated parties and society and discusses ways of measuring those costs. Section 3 compares the analysis of confidentiality costs in this section to the analyses of confidentiality costs presented previously by ICF (ICF 1980) and by RRS (CMA 1981).

1. Types of Confidentiality Costs and Methods of Measuring Those Costs

There are three different types of confidentiality costs incurred by regulated parties. These three types are:

- Cost 1: Out-of-pocket expenditures by submitters due to procedural and administrative requirements.
- Cost 2: Disclosure of trade secrets due to the amount and nature of cost information made public.
- Cost 3: Uncertainty about what kinds of information EPA will require and how much of that information might be disclosed.

A more detailed description and method of measuring each of these costs is provided as follows:

a. Cost 1: Out-of-Pocket Expenditures by Regulated Parties.

These are the procedural or administrative costs which the submitter must absorb in complying with the confidentiality requirements of section 5. The largest component is the labor time required to complete forms and to furnish information (i.e., generic information) required by EPA's confidentiality procedures. These costs include the actual time required to fill out the forms (i.e., the purely procedural tasks), time spent in consultation with EPA representatives, and time spent on internal consultation.

Data on hours required for substantiating confidentiality for the EPA79 form and the CMA79 form are available from ADL (1979) and CMA (1981). These data can be used with ICF's labor rate estimates (see Chapter III, Section B) to provide monetary estimates of out-of-pocket expenditures for each option.

b. Cost 2: Disclosure of Trade Secrets.

EPA's confidentiality policy will affect the probability that trade secrets will be disclosed. Trade secrets are a very important factor in the chemical industry and are sometimes critical to the new chemical introduction process. This is particularly true because the demand for many chemicals is very price-elastic. Because many substitutes for a new substance may exist, there may be little difference between the successful new chemical and the chemical which fails. Every competitive advantage, therefore, becomes significant to the individual firm. The possession of a trade secret by an individual firm may provide a significant competitive advantage.

Trade secrets are not limited only to the identity of a new chemical. The process by which a chemical is manufactured could be far more significant than its identity. A manufacturer's identity and location may reveal information about the potential market for the new chemical to a competitor. Therefore, the information required in the notice may include many items that the submitter would not otherwise reveal.

The distinction between what will and will not lead to the disclosure of confidential business information (CBI) directly or indirectly may frequently be a point of contention between EPA and the submitter. The cost of potentially reduced or destroyed competitive advantage must be included in the evaluation of confidentiality issues and options.

There are several ways in which trade secrets might be disclosed to competitors. The confidentiality rules may be such that the firm is not permitted to claim confidentiality for items whose disclosure would reveal trade secrets. EPA may deny claims of confidentiality and disclose the information to the public, thereby revealing trade secrets to potential competitors. Finally, confidential information may be inadvertently disclosed by EPA.

The only threat of trade secret disclosure from the first source is from disclosure of chemical identity as part of a health and safety study. Except for this item, a submitter can claim confidentiality for any item in a PMN submission. The costs of disclosure from this source cannot be estimated quantitatively. However, the importance of this problem is roughly measured here by determining how often chemical identity is claimed confidential in a submission which includes health and safety data. The relative costs of the reporting alternatives are assessed by determining whether this issue is treated differently under any of the three forms.

Disclosure of trade secrets from the second source, EPA's denial of confidentiality claims, should be virtually nonexistent under any of the options. Denial of confidentiality claims has been a very infrequent event under TSCA. Thus far, only about a dozen submissions have been affected, and 90 percent of the claims in those submissions were approved. In addition, according to Jim Nelson of the Office of General Counsel (April 1982), all of the denials occurred during the first six months of the program.

The costs of disclosure from the third source, inadvertant disclosure of confidential information, also cannot be estimated quantitatively. However, the importance of this problem is estimated by surveying the public files for confidentiality breaches. In the course of its study, the Regulatory Research Service for CMA (CMA 1981, p. III-28) surveyed the public files for confidentiality breaches, and discovered confidentiality breaches in about 5 percent of the files reviewed.

c. Cost 3: Uncertainty About EPA Decisions.

The submitter cannot ignore the potentially adverse situations which may arise from an unfavorable (in the submitter's view) determination by EPA concerning the confidentiality claims asserted. Therefore, preparations may have to be made for each such situation or at least for the most likely situations. Such preparations divert some of the submitter's resources that could be used for other purposes if this contingency planning or preparation were not required.

The costs of uncertainty about EPA decisions on confidentiality cannot be quantitatively measured. However, an indication of whether uncertainty is high or low under interim policies is obtained by examining the records on EPA denials of confidentiality. If denial of confidentiality has been frequent, uncertainty about the status of confidential claims is likely to be high. If denial has been infrequent, uncertainty is likely to be low. Submitter uncertainty about EPA decisions on confidentiality should be virtually nonexistent under any of the confidentiality options. As discussed above EPA has not denied a confidentiality claim since six months after the start of the PMN program. Thus uncertainty will almost certainly be low.

2. Factors That Affect Confidentiality Costs

The costs of confidentiality are affected by several elements of the PMN reporting form. These elements are:

- The number of items for which confidentiality must be substantiated;
- The amount of substantiation required per item declared confidential;
- The timing of substantiation;
- The requirements for generic masking; and
- The disclosure of chemical identity as part of a health and safety study.

Each of these elements and its influence on costs is discussed in greater detail below. The effects of the element on the costs identified above are given only in terms of the direction of the effects. Estimates of the magnitude of the costs are presented in Chapter IV.

The number of items for which confidentiality must be substantiated refers to the fact that EPA may require substantiation for some claims of confidentiality, but in other cases may accept the submitter's assertion without substantiation. The greater the number of items that require substantiation rather than assertion, the greater the out-of-pocket expenditures by both EPA and the submitter, and the greater the cost of uncertainty. Disclosure of items which might reveal trade secrets is also likely to be greater if more items require substantiation. Because the cost of confidentiality assertion is greater if substantiation is required, a substantiation requirement could tend to inhibit confidentiality claims, thereby increasing disclosure of items which might provide useful information to competitors.

The amount of substantiation required for each item declared confidential refers to the volume and detail of information that must be presented to substantiate a claim of confidentiality. At one extreme, substantiation might consist of answers to a long series of specific questions about each item for which confidentiality is claimed. Alternatively, substantiation might consist of a shorter, more general statement encompassing several items or all items for which confidentiality is claimed. The effects of increasing the amount of substantiation on costs are in the same direction (i.e., positive or negative) as the effects of requiring substantiation rather than assertion.

The timing of substantiation refers to whether substantiation is required at the time of submission, or can be postponed until an FOIA request is made for the material. If substantiation is not required until an FOIA request is made, out-of-pocket expenditures by EPA and submitter will be reduced to the extent that not all submissions are subject to FOIA requests. (ICF's review of PMN files showed that about 17 percent were subject to FOIA requests.) Even if substantiation was eventually required for all submissions, out-of-pocket expenditures by EPA and submitters would still be reduced, because the expenditures required for substantiation would be postponed and because the requests might be specific to certain items in the submission. If substantiation is not initially required, uncertainty would be reduced because EPA would not be able to deny confidentiality until an FOIA request was made.

The requirements for generic masking refers to the requirement that submitters supply generic information to the public if certain items of information are held confidential. For example, if the exact location of the submitter is held confidential, the submitter might be required to supply information on the geographic area in which the firm is located. Another example is the requirement that the submitter provide generic chemical names to EPA if confidentiality is claimed for chemical identity. The requirement for generic information adds to the out-of-pocket expenditures of both submitters and EPA.

The disclosure of chemical identity as part of a health and safety study refers to one option being considered by EPA, which would disclose the specific chemical identity of a confidential new substance after the commencement of manufacture if a health and safety study on that chemical is part of the submission. Disclosure of the identity of the substance as part of a health and safety study leads to the disclosure of trade secrets if the identity is held to be confidential and the identity is not masked.

3. Comparison to Previous Analysis

In a previous analysis of confidentiality costs, ICF addressed the three costs identified above to submitters (ICF 1980 Part II, pp. 115-140). In discussing the options, all the factors identified above were taken into account, except the number of items for which confidentiality must be substantiated.

In its critique of the ICF analysis, RRS stated that ICF considered all aspects of confidentiality costs (CMA 1981, p. III-20). However, RRS contended that ICF did not use the best data available for estimating those costs (CMA 1981, p. III-21). Specifically, RRS suggested that ICF could have improved its analysis by taking the following steps:

- analyze the confidentiality claims made in PMN filings to determine the amount of effort expended by regulated parties in making confidentiality claims;
- survey the public files for breaches of confidentiality; and
- survey submitters on the costs of confidentiality claims.

Since the completion of the previous ICF study, ICF has analyzed the confidentiality claims made by submitters. Although ICF has not conducted a survey of submitters, the survey conducted by RRS has been used in this analysis. These estimates are presented in Chapter IV, Section D.

E. EXPECTED COSTS OF EPA-INDUCED RESTRICTIONS

Beyond direct form-filing costs, delay costs, and confidentiality costs, submitters are concerned over the possibility of incurring additional costs because of some EPA action taken in response to a PMN submission. This section defines these costs and suggests an approach for quantification. The actual estimates are provided in Chapter IV, Section E.

In 27 cases, notice submitters have taken some action to gather data or to reduce the risk from production or use of new chemical substance as a result of the section 5 process. In 15 other cases, submitters have withdrawn notices and cancelled plans for introducing new substances as a result of the section 5 process. In each case the action was taken voluntarily in the sense that the submitter was not legally compelled to take action. But in each case, the action was taken to forestall EPA from placing restrictions on production of the chemical. In some of the 15 cases in which the notice was withdrawn, EPA formally had begun section 5(e) proceedings to obtain additional information (e.g., the Agency had begun to draft the notices) before commercial introduction of the chemical, and in the rest of these 15 cases, section 5(e) action was planned by EPA but not yet initiated. In the other 27 cases, the submitters' actions were taken to alleviate concerns expressed by EPA, and to forestall possible future legal action. Even though the actions were in some sense voluntary, they probably would not have been taken as soon, if at all, in the absence of section 5. Therefore, the costs of these actions are costs of the section 5 process to submitters and reflect the concerns of submitters with costs imposed by EPA actions taken in response to a PMN submission.

Five types of actions were taken by these 42 submitters.[5]

- toxicological tests were conducted on 15 substances;
- 15 substances were withdrawn;
- labels were developed for 9 substances;
- Material Safety Data Sheets (MSDS) were developed for 9 substances; and
- 3 substances were reformulated.

In the remainder of this section, methods for measuring the costs of each of these actions are developed.[6]

1. Toxicological Testing

Estimates of the cost of toxicological testing can be obtained from a 1979 survey of toxicological testing labs (Enviro Control 1980). These estimates, updated to 1981 dollars, are used to estimate the costs to regulated parties of the toxicological testing induced by section 5.

2. Withdrawal

The cost of withdrawal is the value of profits foregone and this can be measured in two ways. When specific chemical information is available, the net present value of the expected profits based on price sales, and margin data can be computed. When specific chemical data is not available it is possible to estimate the maximum net present value of profits from estimates of research and development spending on new products. In the subsequent paragraph values based on both approaches are developed.

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[5] The total below sums to more than 42, because more than one action was taken for several substances.

[6] The costs discussed here refer to the costs of the actions themselves, not the costs of any negotiations leading up to those actions.

For a specific chemical affected by EPA action, the foregone profits can be estimated using the following algorithm and data provided in the PMN:

- for each year of foregone production, estimate the annual production volume, and selling price, and return on sales (based on market analysis);
- for each year, compute foregone profits as the product of production volume, price, and return on sales;
- discount the stream of profits using an appropriate discount rate (based on the submitters cost of capital);[7]
- sum the discounted profit stream to obtain the present discounted value of profits foregone as a result of withdrawal.

Estimates of expected first, second, and third year production volume are obtained from the section 5 notice for each substance, and can be used as estimates of actual production volume for these. In the absence of additional information, production volumes after the third year are assumed to be equal to expected third year production volume. This procedure underestimates future production volume for some chemicals which are much more successful than anticipated, but overestimates future production for other chemicals, which fail to become commercially viable.

CSMA (Heiden & Pittaway 1982) asked companies what their expected profits per new chemical were for a set of recently introduced chemicals. Using the results of their very limited survey, ICF found that the average was $438,500 in net present value terms with a standard deviation of more than $474,000.[8]

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[7] If real prices are used, a "real" discount rate is appropriate. If nominal prices are used, a nominal discount rate is appropriate.

ICF used NERA data to derive an estimate of $560,400 per new chemical. From Table 6.1 of NERA's study (NERA 1981), we obtained R&D costs of 225.9 thousand dollars per successful chemical. Because successful chemicals must cover the cost of R&D costs of all new chemicals (including those that fail) we divided by the ratio of R&D costs on all ventures to R&D costs on successful ventures (1/.403) to obtain R&D cost to be covered by the average new chemical of $560,400. Based on the assumption that the profits from R&D over time, adjusted for the time value of money, must at least equal the amount invested in the new chemical (otherwise no one would invest in R&D), we concluded that $560,400 is another reasonable estimate of the minimum expected profits per new chemical innovation.

We have used the estimate of $438,500 to $560,400 in Chapter IV as an average value for profits foregone due to withdrawal.

3. Labeling

The cost of labeling depends on whether an alteration to an existing label is required or a new label must be created. If the submitter had already planned to label the product, and the section 5 process causes that label to be altered, the cost of labeling is virtually nonexistent.[9] If the section 5 process causes a product to be labeled that would otherwise not have been labeled, new plates for the label must be prepared, and the labels themselves prepared from the plates. Estimates of the cost of preparing plates and labels can be obtained from a previous ICF study (ICF n.d.). The total cost of labeling for each product equals the initial cost of the plates, plus the present discounted value of the stream of label preparation costs. This method is used to estimate the costs of label changes made due to section 5 actions.

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[8] Derived by taking the average of the minimum expected profits and maximum expect profits at a 15 percent discount rate from Exhibit B-III for the 38 surveyed innovations.

[9] This statement assumes that at the time the change is made, the plates for the label have not been prepared.

4. Material Safety Data Sheets (MSDS)

The cost of preparing an MSDS has been estimated by the Occupational Safety and Health Administration (ICF n.d.), and this estimate is used for the cost of the MSDS changes caused by the section 5 process. Use of this figure will result in an overestimate of the costs of the section 5 process, because in some cases only marginal changes in existing MSDS were required. Unfortunately no acceptable method for estimating the marginal effect exists.

5. Reformulation

Reformulations are very specific to particular chemicals and chemical process. Without specific chemicals to analyze it is not possible to accurately estimate reformulation costs. Therefore, we have not provided estimates of the cost here. We do provide an estimate of the number of reformulations expected annually.

F. COST TO EPA

Section 5, like any regulation, not only imposes costs on industry but also imposes costs in the form of government resources used to implement it. In this case these costs take the form of personnel and overhead cost to process and review the PMNs. These government costs contribute to either higher taxes or higher deficits which detract from economic growth and therefore represent real resource costs. In this section estimates of the costs to process a single PMN and a single exemption form are presented. These estimates were developed by EPA staff in the course of preparing the exemption analyses. Appendix C provides a description of EPA's PMN review procedures The costs of the reviews are discussed as follows.

1. Estimated Cost Per Review

Just as labor cost, labor overhead, and labor hours drive estimates of the industry cost to complete the form so too does the amount of government labor, its associated overhead, and the hours required drive estimates of the cost to government to review PMNs. In addition government contracts resources (extramural funds) devoted to the process must be added to the cost per review.

In Appendix D to "Economic Impact Analysis of TSCA section 5(h)(4) Exemptions: Low Volume Chemicals" (Ng 1982), Ng estimated the average staff salary at $35,000 per year, excluding overhead, in 1981. Government benefits and overhead were estimated at 50 percent. Finally an adjustment was made for the annual cost for the number of direct person-months a government employee worked annually (10.4). Thus a cost per direct person month of $5,050 or $29.13 per hour was obtained[10].

This cost of labor must be multiplied by the amount of labor necessary to review PMNs to arrive at a cost per PMN. In Appendix D, Ng also provided Agency budget data that showed the number of person-months annually devoted to each activity. Exhibit III-3 shows how this breaks out among the four activities.

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[10] These costs, derived in 1981 from EPA 1982 budget planning documents, do not include certain management, policy, and clerical staff costs associated with the program. Also, not reflected in this estimate are the rent, utilities, and other physical property costs of the program.

EXHIBIT III-3

IN-HOUSE PERSON-MONTHS BY ACTIVITY FOR PMN REVIEW*

Document Control and In-House Tracking	110.2
Initial Review	391.9
Detailed Review	280.4
Section 5 Control Actions (5(c), 5(e))	8.0
Total	790.5

*Variable cost only.

At present 64 percent (502.1 out of 790.5 person-months) of Agency PMN-devoted resources go toward tracking and control and toward initial review of chemicals. Thirty-six percent is devoted to scrutinizing those chemicals that potentially pose significant human health and environmental effects. Because an average PMN review cost is needed for this analysis, the total person-months divided by the number of PMNs received annually can be used to develop Agency cost to review an average PMN. Thus, assuming 800[11] PMNs per year and 790.5 person-months expended on the PMN process annually, it takes .988 person-months per PMN. Multiplying this by a cost per person-month of $5,050 comes to $4,989/PMN of Agency personnel resources.

PMN review may require significant extramural costs along with Agency personnel costs. Annual extramural Funds for initial review total $1,109,000; for detailed review, $1,024,000; for section 5 controls $28,000; and for in-house tracking $30,000. No extramural funds are used for document control. In total $2,191,000 are spent extramurally on the PMN process. Dividing this by 800 PMNs comes to $2,739 per PMN.

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[11] For consistency with PMN exemption analysis 800 PMNs is used here. In performing the cost analysis in Chapter IV we assume 900 PMNs annually. The 800 estimate was the Agency's expectation at the time of the exemption analysis. Currently 900 is their estimate.

Altogether Agency personnel costs plus extramural costs total an average of $7,728 per PMN ($4,989 + $2,739).

2. Wide Variation in Actual Cost

The average cost shown above can be misleading because the range of potential cost to review a PMN is very large, and is primarily a function of the potential hazard posed by the PMN chemical. Although all PMNs are subject to document control, in-house tracking, and initial review costs, only five percent of PMNs require detailed reviews; and only .25 percent of PMNs are subject to section 5 control actions. This means that the "typical" PMN review does not incur detailed review and section 5 control costs. However, the relatively few "problem" chemicals require tremendous resources to review.

To estimate the typical costs and the problem chemical costs, we multiply the percentages in each category by the number of PMNs submitted annually, and then match the number of PMNs to the activities. By dividing the counts into the cost of the activity we obtain cost per PMN for that activity.

EXHIBIT III-4

NUMBER OF PMNs INVOLVED IN EACH ACTIVITY, ANNUAL COSTS, AND COST/PMN

	PMNs	Total Cost* (personnel plus extramural)	Cost/ PMN
Document Control and In-house Tracking	800	$586,510	$733
Initial Review	800	$3,088,095	$3,860
Detailed Review	40	$2,440,020	$61,000
Section 5 Control Actions	2	$68,400	$32,200
		$6,183,025	

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*Variable cost only.

As shown in Exhibit III-5, the cost per PMN for the typical chemical is only $4,593.[12] For a chemical that undergoes detailed review and does not have section 5 control action taken against it, the cost is $65,593. For the acted-upon chemical the total cost is $99,793. Thus the range of potential cost to government is $4,593 to $99,793 per PMN. In subsequent analysis, these different estimates will be used to estimate government savings associated with different programs.

EXHIBIT III-5

EPA COST TO PROCESS DIFFERENT TYPES OF PMNs*
(1981 Dollars)

	Typical Chemical	Detailed Review Chemical	Section 5 Controlled Chemical
Document Control/ In-house Tracking	$733	$733	$733
Initial Review	$3,860	$3,860	$3,860
Detailed Review		$61,000	$61,000
Section 5 Control Action	____	____	$34,200
Total	$4,593	$65,593	$99,793
Annual Number of PMNs	760	38	2

*Variable cost only.

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[12] There is evidence to suggest that the document control, in-house tracking, and initial review activities require less expensive labor than the detailed review and section 5 control activities. This aspect of the analysis was not pursued because data were insufficient to develop labor cost specific to activities.

3. Cost to EPA to Review Exemption Notices

In Appendix E of "Economic Impact Analysis of TSCA section 5(h)(4) Exemptions: Polymers" (Luttner 1982), Luttner found that the average costs to review a 14-day exemption notice was $1,483. The average cost to review a zero-day notice was $640. For purposes of this analysis we assume that the review of a photographic exemption requires labor equal that need for a 14-day polymer ($1,483).

These estimates were developed on the basis of an exemption review process that included that following activities:

- log-in and tracking
- inventory check (14-day review only)
- literature review
- SAT/PERT[13] review
- disposition decision

Based on recent EPA experience processing PMNs, Ng estimated the person-months/notice to perform each activity at .11, .04, .02, .15, and .07 respectively (Ng 1982 Appendix E). It was assumed that a zero-day review would not include a literature review, SAT/PERT review, or inventory check; but a 14-day review would include all activities. Ng also assumed average salaries for each step that amount to $26,385 for a 14-day review, and $20,182 for a zero-day notice. In Chapter IV, these estimates will be used to compute the savings to EPA of alternative regulatory programs.

4. Summary

The Agency estimated the cost of reviewing PMNs and proposed exemption notices in its analyses of exemption alternatives. This section presented those estimates, adjusting the PMN review costs for the type of PMN. The estimated costs to review the various forms were:

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[13] SAT is the acronym for Structure-Activity Team. PERT stands for Preliminary Exposure Review Team.

EXHIBIT III-6

COST PER NOTICE TO REVIEW PMN AND EXEMPTION NOTICES*

(1981 Dollars)

Typical PMN	$4,593
Detailed Review PMN	$65,593
Section 5 Control Action PMN	$99,793
Average PMN	$7,728
Zero-day exemption notice	$640
14-day exemption notice	$1,483

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*Variable cost only.

CHAPTER IV

IDENTIFICATION AND ANALYSIS OF REGULATORY OPTIONS

This chapter provides estimates of the direct costs of compliance for each of the regulatory options. It is organized as follows:

A. Background
B. Analysis of Costs of the EPA79 form
C. Analysis of Costs of the CMA79 form
D. Analysis of Costs of the EPA82 form
E. Comparison of Costs of Alternatives
F. Effects of Proposed Exemptions Policies on Program Costs
G. Cost to Government
H. Other Costs
I. Chapter Summary

For each regulatory option, the annual costs identified in Chapter III (form-filing costs, confidentiality costs, delays costs, and costs of restrictive action) are computed in Sections B, C, and D. The three regulatory options are compared in Section E. Section F addresses the effects of an exemption program, such as the one recently proposed.[14] The costs to the federal government of administering the PMN program are discussed in Section G, and other costs are discussed in Section H. Finally, a chapter summary is provided in Section I.

A. BACKGROUND

Section 5(a)(1)(A) of the Toxic Substances Control Act (TSCA; Public Law 94-469) requires manufacturers of new chemicals to provide the Environmental Protection Agency (EPA) with written notice of their intent to produce such substances at least 90 days prior to when actual manufacturing begins. Any chemical not listed on an inventory of existing chemicals (the "Inventory")[15] is considered "new" for premanufacture notice (PMN) purposes. The PMN program, which became effective July 1, 1979, involves the submission of information on new chemicals to EPA. TSCA requires the submitters to supply the chemical's common/trade name, identity and molecular structure, estimated production quantities, uses, disposal methods, workplace exposure and release information, and a listing of impurities and byproducts. Data concerning the effect of the chemical on human health or the environment in the manufacturer's control or reasonably ascertainable by the manufacturer must also be submitted. Once EPA receives the PMN, it must publish notice of receipt in the Federal Register and conduct its evaluation of the chemical based on the data provided and other available information. The submitter may produce the chemical at the end of the 90-day review period unless EPA takes action to regulate the substance or orders the review period extended for an additional 90 days for good cause.

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[14] The policy being analyzed embodies the regulatory provisions of the following final and proposed regulations:

Premanufacturing Notification: Exemption of Chemicals Used in or for the Manufacturing or Processing of Instant Photographic and Peel-Apart Film Articles. (47 FR, 24308).

Premanufacturing Notification: Proposed Exemption for Site-Limited Intermediate Chemical Substances and Chemical Substances Manufactured in Quantities of 10,000 Kg or less. (47 FR, 33896).

Premanufacturing Notification: Proposed Exemption for Polymers. (47 FR 33924), August 4, 1982.

See also: Ng 1982, Warhit 1982, and Luttner 1982.

[15] The Chemical Substance Inventory is a list of all chemicals that were manufactured, imported or processed for a commercial purpose since January 1, 1975. The Inventory is maintained under statutory authority of section 8(b) of TSCA.

Premanufacture notification also applies to significant new uses of existing chemicals. Should EPA find, by rule, that a new use of an existing chemical presents significant new exposure to humans and/or the environment, the manufacturer or processor must report through the PMN process. The 90-day review period also applies in this case.

Section 5(d)(1) of TSCA specifies PMN data requirements. EPA proposed a set of regulations interpreting these requirements in January 1979 and issued a reproposal (EPA79) in October 1979. Both proposals included a PMN form that notice submitters would be required to complete. In response to the January 1979 proposal, the Chemical Manufacturers Association (CMA) also issued suggested PMN requirements. EPA is now in the process of developing a EPA82 form. Firms are not now required to use any of the proposed or suggested forms. In practice, PMN submissions to date include a wide range of information and there is a considerable amount of post-submission communication between EPA and chemical firms to obtain additional data for Agency review purposes. Appendix D compares the three reporting options which are addressed in this analysis.

EPA has recently projected the rate of PMN submissions for the next few years based on historical experience and other relevant information (Luttner and Shapiro 1982). Historical PMN submissions have been as follows: 281 submissions for fiscal year (FY) 1980, 580 submissions for FY 81, and 408 for the first six months of FY 1982. Using a linear regression based on quarterly data, the projected annual rate of PMN submissions for FY 1982 is 900. It is this rate which has been assumed for estimating annual costs associated with all three regulatory options. Although it may be possible that the rate of PMN submissions could vary with the regulatory options, the constant rate of 900 per year has been assumed here for two reasons:

- no historical data exists regarding how the rate of PMN submissions would change (if at all) with the regulatory options;
- any prospective estimates would necessarily be speculative on an individual PMN basis.

However, the analysis of Section F (Exemptions Analysis) concentrates on estimating how the rate of PMN submissions will change under various exemptions policies. This analysis was based on characteristics of historical PMN submissions.

B. ANALYSIS OF COSTS OF THE EPA79 FORM

The EPA79 form requires submitters to provide the most information of any option analyzed here. The specific information required is listed in Appendix D. Appendix G provides a copy of this form. As shown in Appendix D, the major areas for which information is sought are: submitter's identity, chemical identity, generic names, production and marketing data, transport, risk assessment, detection methods, human exposure and environmental release at sites controlled by the submitter and at sites controlled by other firms manufacturing the chemical, consumer and commercial use exposure, confidentiality attachment, and a federal register notice. Physical and chemical properties and health and environmental effects data would be submitted as test data. The submitter is free to provide any other information.

1. EPA79 Form Filing Costs

Appendix G provides a copy of the proposed EPA79 form. Exhibit IV-1 shows the hours estimated in previous EPA-commissioned analyses to complete each section of the EPA79 form (ADL 1979). Using the labor rates developed in Appendix A of $17/hour clerical, $43/hour technical and $67/ hour managerial, the EPA79 form costs $1,800-$14,600 (December 1981 labor rates) to complete. The total annual cost to submit 900 PMNs would be $1,620,000 to $13,140,000.

The range of costs is quite wide because hours estimates for several of the items on the form were large. As mentioned in Chapter III, these estimates have a large range because the potential submitters vary greatly in their style of operations, efficiency, and approach to completing the forms.

2. Confidentiality Costs of the EPA79 Form

This section presents estimates of the costs of the confidentiality under the EPA79 form in each of three cost categories identified in Chapter III: out-of-pocket expenditures by submitters, disclosure of trade secrets, and uncertainty. In some cases, quantitative estimates of the costs are made. In other cases, limitations in the available data permit only qualitative estimates of costs to be made.

EXHIBIT IV-1

EPA79 FORM: ADL ESTIMATES OF LABOR REQUIREMENTS

Section of Notice	Labor Requirements (Hours)		
	Clerical	Technical	Managerial
I. General Information	2-10		
A. Manufacturer Identification			1-8
B. Chemical Identity			
1. Class I Chemical Substance a/		1-4	0
2. Class II Chemical Substance a/		1-4	0
3. Polymers a/		1-5	0
4. Impurities		1-8	0
C. Generic Names		0-4	0-1
D. Production and Marketing Data			1-2
1. Production Volume		1-4	
2. Category of Use		1-8	
3-4. Previous Manufacture and Hazardous Warnings		1	
5. Customers		0-8	
E. Transport		1	0
F. Risk Assessment		0-16	0-2
G. Detection Methods		1-4	0
II. Human Exposure and Environmental Release	4-20		
A. Industrial Sites Controlled by the Submitter			2-6
1. Process Information		1-4	
2. Block Diagram		1-24	
3. Occupational Exposure			
3.1-3.2 Identity of Site and Occupational Exposure at Site		2-16	
3.3-3.5 Direct Exposure, Physical State, and Other Substances		2-16	
4. Environmental Release and Disposal		1-12	

EXHIBIT IV-1 (continued)

EPA79 FORM: ADL ESTIMATES OF LABOR REQUIREMENTS

Section of Notice	Labor Requirements (Hours) Clerical	Technical	Managerial
B. Industrial Sites Controlled by Others			0-2
1. Process Information--Identity of Site		0-2	
2. Process Description		0-14	
3. Occupational Exposure		0-20	
4. Environmental Release and Disposal		0-8	
C. Consumer and Commercial User Exposure			0-2
1. Table--Route, Frequency and Number Exposed		0-16	
2. Exposure Levels		0-4	
3. Product Aspect Affecting Consumer Exposure		0-4	
4. Byproducts of Use		0-4	
III. List of Attachments	1-8		
A. Physical and Chemical Properties Data		4-16	1-4
B. Health and Environmental Effects Data		8-40	2-8
C-D. Notice Attachments, Confidentiality Attachments and Voluntary Attachments		0	0
IV. Federal Register Notice	1-2	1-8	1-2
Total	8-40	27-267	8-37

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[a] Every chemical is either in Class I, Class II, or is a polymer and therefore, only one of subsections I.B.1, I.B.2, and I.B.3 will be submitted. Thus, only one of these subsections was chosen because it reflects both the minimum and the maximum possible labor requirements needed for a chemical substance.

Source: ADL 1979, pp. 32-38.

a. Out-of-pocket expenditures by submitters.

Estimates of the cost of asserting and substantiating confidentiality have been made by Arthur D. Little, Inc. (ADL 1979) and by Regulatory Research Service (CMA 1981). ADL estimated the cost of confidentiality for the EPA79 form by estimating, on the basis of its knowledge of the chemical industry, how many hours of clerical, technical, and managerial labor it would take to assert and substantiate claims of confidentiality. ADL divided the substantiation process into four stages. Those stages and the labor hours associated with them are shown in Exhibit IV-2.

EXHIBIT IV-2

ESTIMATED CONFIDENTIALITY PROCESS HOURS

Stage	Hours
Strategy Development	2 - 24
Substantiation Development	12 - 100
Form Preparation	2 - 16
Review	2 - 20
Total	18 - 160

Source: ADL 1979, p. 52.

The first stage, strategy development, involves determining which elements of information on the PMN form to claim as confidential, including categories of claims and linkages. The time required for this stage was estimated as 2-24 hours. The second stage, substantiation development, involves developing responses to questions or requirements in each EPA category claimed confidential, determining the appropriate linkages, and obtaining certification of the claims by corporate management. The time required for this stage was estimated as 12-100 hours. The third stage, form preparation, involves preparing sanitized attachments, and making annotations on the complete PMN form to indicate confidentiality assertions. The time required for this stage was estimated as 2-16 hours. The fourth stage, review, involves reviewing the completed PMN form and "sanitized" attachments with in-house staff. The time required for this stage was estimated to take 2-20 hours. The total hours required for assertion and substantiation of confidentiality were estimated to be in the range of 18-160 hours.

ADL did not divide these hours into clerical, technical, and managerial hours, as it did when costing the form. Instead, it applied an average labor rate of $50 per hour to the low end of the range and on average labor rate of $40 per hour to the high end of the range, resulting in a cost estimate of $900-6,400. The difference in the hourly rates reflect a higher management content in the 18 hour estimate, and a higher proportion of technical and staff participation in the 160-hour estimate.

RRS conducted a survey of (CMA 1981) notice submitters in 1980 which gathered information on, among other things, the costs of asserting and substantiating confidentiality. Based on a sample of 112 submissions for which usable information on confidentiality costs was obtained, RRS calculated the mean cost of asserting and substantiating confidentiality at $1,137 (at the labor rates used by the firms themselves) or $1,333 (at average labor rates). RRS found statistically significant differences in confidentiality costs among firms of different sizes and product segments, but costs did not differ by type of form used.

The estimates of confidentiality costs used here are based on the RRS data rather than the ADL data for several reasons. The ADL data indicate a range of possible costs, depending on factors such as the importance of confidentiality to a submitter's competitive strategy. In order to obtain an estimate of mean cost from that range, it is necessary to know how submitters are distributed over that range. The use of the RRS data obviates that problem. It should be noted that the RRS and ADL estimates seem to be in rough agreement. It is true that the RRS estimate falls close to the bottom of the ADL range, but the RRS estimate includes those submitters who made no confidentiality claims, about 16 percent of the total. In addition, the highest cost reported in the RRS survey, $5,320, is relatively close to the top of the range estimated by ADL.

The RRS estimate of mean confidentiality costs for submitters, after several adjustments (described below) is taken to be the estimate of confidentiality costs of the EPA79 form. Although this form had not been adopted at the time that the survey was taken, it had been proposed, and analysis of a sample of about 500 PMN submissions reveals that the vast majority of the submitters in the sample used the proposed form. This does not necessarily mean that submitters devoted as much care to substantiating confidentiality as they would have if the EPA79 form had become final. In fact, examination of the submissions suggests that current substantiations often are not as extensive as contemplated under the EPA79 form. On the other hand, confidentiality costs should decline as submitters gain more experience. This argument is also supported by an examination of the notices, which reveals that firms often use an identical substantiation for several notices. Without any basis for estimating the relative magnitude of these counteracting effects, it is assumed that they roughly cancel each other out.

RRS estimated confidentiality costs at the labor rate actually used by the firms rather than the average labor rates used here. Average labor rate costs, not used by RRS, are useful for prospective analyses; but if an estimate of the resources actually spent by submitters is desired, the firms' own labor rates should be used. This analysis is a prospective one so that average costs are more appropriate here.

The RRS estimate of $1,133 per submission must undergo three adjustments before it can be used in this analysis. The three adjustments are:

- the incorporation of post-submission labor costs and other direct costs;
- a correction for size bias in the RRS sample; and
- a correction for inflation between the time of the survey and the present.

In its report, RRS stated that its estimate understates confidentiality costs because post-submission confidentiality labor costs were not estimated separately from other post-submission costs, and therefore could not be incorporated into the estimate of confidentiality costs. In addition, some of the non-labor costs involve confidentiality, and must also be added to confidentiality labor costs to estimate the full costs of confidentiality. In order to incorporate these costs, it is assumed that post-submission labor costs and other direct costs (both pre-submission and post-submission) are divided between confidentiality costs and costs of completing the form in proportion to the division of pre-submission labor costs between those two categories. As shown in Exhibit IV-3, the sum of the average post-submission labor costs, pre-submission other direct costs, and post-submission other direct costs is $1,659. Allocating this between form submission costs (78.5% of the total) and confidentiality costs (21.5% of the total) means that an additional $358 should be added to the $1,133 in confidentiality costs, for a total of $1,491.

EXHIBIT IV-3

RRS ESTIMATES OF COSTS OF SUBMISSION, FIRM LABOR RATES
(1980 Dollars)

Type of Cost	Amount
Post-Submission Labor Costs	$ 440
Other Pre-Submission Costs	1,157
Other Post-Submission Costs	62
Subtotal	$1,659
Form Submission Labor Costs	4,134
Confidentiality Labor Costs	1,133
Total	$6,926 [a]

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[a] This figure differs from the figure of $6,954 given for total PMN cost on Exhibit 3-2 of the RRS report. No explanation for the difference between the two figures could be uncovered.

Source: CMA 1981.

Although data on "other" costs from the RRS survey (CMA 1981) have been incorporated here without alteration, it is likely that the estimates in the RRS survey significantly overestimate the actual level of "other" costs under any of the options. Examination of the RRS data reveals that a disproportionate share of the costs identified in the survey was incurred by a few submitters. For example, just over 40 percent of the pre-submission "other" costs were incurred by 2 of the 112 submissions, and another 37 percent by another 6 submissions. If these eight submissions are removed, mean pre-submission "other" costs equal $276 rather than $1,157. With post-submission "other" costs, the situation is even more extreme. One submission accounts for over 57 percent of total post-submission "other" costs. Without that submission, the mean for "other" post-submission costs equal $26, rather than $62.

RRS identified other costs as "the cost of hiring special consultants; cost of travel to EPA to deal with special problems raised by the submission; telephone costs, etc." It is likely that the bulk of the "other" costs are accounted for by the first two categories, but these costs should substantially diminish with the passage of time. Nevertheless, these costs have been fully incorporated in the ICF estimates.

The above estimate must also be corrected for the size bias in the RRS survey. As RRS stated, the size distribution of firms in the survey is different than the size distribution of submitters. Because PMN costs differ by size of firm, average cost for the population will differ from average cost for the sample. Using the procedure described in Appendix A of the RRS report (CMA 1981) to adjust the estimate of $1,491 results in an adjusted estimate of $1,471 for confidentiality costs.

The final adjustment takes account of inflation since the RRS survey was completed. The survey was mailed on December 10, 1980. Although the dates of the notices surveyed are not known, it is assumed that the firms are referring to costs incurred in mid-1980. Because the cost estimates developed here refer to December 1981, the above estimate must be adjusted for inflation between mid-1980 and December 1981.

ICF has developed inflation rates for clerical, technical, and managerial hours, but they cannot be used directly because the costs are not separated into those components. An overall inflation rate of 12.5 percent per year is consistent with the ICF labor rate inflation estimates. Using this inflation estimate, between mid-1980 and December 1981 costs increased by 19.3 percent. Therefore, the estimate of confidentiality costs per submission under the EPA79 form in December 1981 dollars is $1755 ($1471 times 1.193).

The EPA79 form requires all substantiation to be provided with the initial submission. Thus, the full cost estimate of $1755 is incurred. For 900 PMNs annually the cost would be $1,579,500.

b. Disclosure of Trade Secrets.

Under the EPA79 form chemical identity may be disclosed as part of health and safety study. Although quantitative estimates of the cost of disclosure from this source cannot be made, some idea of the importance of this problem can be determined by examining the number of submissions which contain health and safety studies,[16] and for which chemical identity is claimed confidential. Of the approximately 500 submissions in the ICF data base, chemical identity was claimed confidential for 70 percent. Of this proportion, 57 percent included either health or environmental data. Therefore, 40 percent of all submissions are potentially affected by the disclosure of chemical identity as part of a health and safety study.

As discussed in Chapter III, disclosure of trade secrets because of EPA's denial of confidentiality claims and because of confidentiality breaches should be extremely infrequent and should not be affected by the choice of form.

c. Uncertainty.

As discussed in Chapter III, submitter uncertainty about EPA decisions on confidentiality should be virtually nonexistent under any of the confidentiality options, because EPA has not denied a confidentiality claim since six months after the start of the PMN program. Denial of confidentiality claims, and uncertainty about the denial, should be virtually nonexistent under any option.

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[16] The definition of "health and safety study" under TSCA includes ecological and environmental studies as well.

d. Summary.

Total confidentiality costs under the EPA79 are expected to be $1755 per PMN. Assuming 900 PMNs per year, the total quantifiable cost of confidentiality of the EPA79 form would be $1,579,500.

3. Direct Delay Costs for the EPA79 FORM

Chapter III, Section C introduced the concept of pre-submission and post-submission delay costs. The direct cost of delay was defined as the present value of profits delayed because of the PMN process. Although it is recognized that the PMN effect (and in some cases primarily the delay component) may lead to sales foregone, these are indirect economic effects that result from the entire PMN impact, and are not addressed in this section. The purpose of Chapter IV is to estimate the size of the direct PMN effect under various options. As with any market adjustment (regulatory or non-regulatory), the change will produce ripples throughout the economy. For PMN, these indirect effects are related to sales foregone resulting from reduced innovation. These are addressed in Chapter V.

In Chapter III, Section C, the following formula for assessing the present value of profits delayed was presented:

$$PD = \left[1 - \frac{1}{(1+r)^t} \right] \cdot PV(p)$$

where

PD = present value of profits delayed due to PMN delay

t = amount of time attributable to PMN delay

r = average real rate of return (specified in the same time units as t)

PV(p) = present value of profit stream associated with the average new chemical.

In the ensuing analysis, values for t will depend upon the options being considered. However values for r and PV(p) must be pre-specified. One estimate for r can be derived from historical returns on stocks and bonds on the theory that real returns (i.e., returns after inflation) on new chemicals must be at least equal to the real returns on these corporate financing vehicles. One noted source has calculated a 52-year average of real returns on stocks and bonds as 6.4 percent and 1.5 percent respectively (Ibbotson and Sinquefield 1979, p. 23). When these returns are weighted by the historical capital structure for the chemical industry (70 percent equity, 30 percent debt) (Value Line 1981), the minimum real rate of return for new chemicals would be 5 percent. Of course, because new chemicals would probably require a real rate of return higher than 5 percent, the ensuing analysis is also performed with a 10 percent real return. In general, the value of delay will be directly proportional to the real rate of return assumed.

In Chapter III two values for the present value of the profit stream were determined. One was based on CSMA data (Heiden and Pittaway 1982); the other on ICF manipulation of NERA/CMA data. Based on the NERA/CSMA data, when discounted at a 5 percent real rate of return (15 percent nominal), the present value of the profit stream of the "average" new chemical was $438,500 (in 1981 dollars). Using this same data a net present value (NPV) of $371.7 thousand is obtained at a 10 percent real rate (20 percent nominal). Based on CMA data the NPV would be $560,400 at the average discount rate of the chemical industry overall.

In this analysis, values for t are based on a sample of 500 PMNs, as explained previously. Those chemicals which were intermediates associated with other PMN chemicals must be subtracted out because there would not be any delay for these chemicals--PMN review would be conducted in parallel with reviews for the final chemical. Also to be subtracted out are those chemicals for which PMN review was never completed because the chemical was withdrawn. There can be no profit streams associated with these chemicals. (Later the costs associated with these losses are discussed.) Based on the sample data, 11 percent of PMN chemicals are in the first category and .75 percent of PMN chemicals are in the second. This leaves 88.25 percent of the PMN chemicals possibly incurring delay.

The estimates of delay costs in this section will be based on 5 percent and 10 percent real rates of return, profit stream present values of $438,500 at 5% (Heiden and Pittaway 1982) and $371,700 at 10% and $560,400 (NERA 1981) (1981 dollars), and values for t derived in Chapter III and number of PMN chemicals from EPA projections of 900 per year.

In theory, pre-submission delays will vary with reporting options. The more stringent the form and the greater the depth of information which must be provided, the longer the pre-submission delay. One source, based on a survey of 37 firms, estimated average pre-submission delay as one month under the EPA79 (CMA 1981, p. III-37). With the CMA79 or EPA82 form, presubmission delay could presumably be less, because these reporting requirements are less comprehensive. However, it is not entirely clear that pre-submission delay would be reduced under these options because many of the most time-consuming requirements (i.e., searching for data an health and environmental effects) remain the same. Therefore, in order to ensure that pre-submission delays are not underestimated for any option, pre-submission delays are set at one month under all three reporting options. With a real rate of return of 5 percent and a present value of profits at $438,500, pre-submission delay is valued at $1805 per chemical. At a real rate of return of 10 percent, using the NPV of the profit stream of $371,700 the appropriate per-chemical pre-submission delay would be $3,072. Using the $560,400 estimate and a 5 percent real return[17] the delay would cost $2,325.

Assuming a submission rate of 900 PMNs per year, annualized pre-submission delay would be valued at the maximum at between $1,624,500 and $2,764,800 regardless of the reporting option chosen.

Post-submission delay will also not change with reporting option. As explained in Chapter III, Section C, post-submission delay will depend on the extent to which PMN review adds to the critical path for commercialization. At a maximum, PMN review will always add 90 days to the critical path for 99.2 percent of chemicals and 180 days to .8% of chemicals. Assuming a 5 percent real rate of return the cost is .992 × 900 chemicals × .8825 × .012 × $438,500 or $4,145,900, plus .008 × 900 × .8825 × .012 × 438,500 or $33,400, for a total of $4,179,300. Assuming a 10 percent real rate of return, the cost is $7,380,500. These two estimates bound post-submission delay.

Together, the pre-submission and post-submission delay cost total $5,803,800 assuming a 5 percent real rate of return, and $10,145,300 assuming a 10 percent real rate of return.

These estimates assumed that every PMN other than those that were withdrawn as well as intermediates, experienced delay. In reality not all chemicals will experience delay. At the extreme (possibly when firms learn to incorporate the PMN review into their product introduction process) delay costs are zero. Obviously, this estimate is as inaccurate as the maximum estimates.

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[17] Five percent is closer to the chemical industry real average discount rate than 10 percent.

Because no data about the percent of products for which the PMN is on the critical path exists, we have created a best guess estimate of the percent based on commencement of manufacture letters. Out of all commencement of manufacture letters received, 39.5 percent are postmarked within 30 days of the end of the PMN review period. Another 31 percent come in between 30 and 90 days after expiration of the review period. However, the Agency is receiving commencement of manufacture notices from only 46 percent of the PMNs submitted. If we assume that all PMN chemicals that commenced manufacture within 30 days after the review period ended were delayed by the process, then total delay costs would be between $1,054,500 (.46 × .395 × 5,803,800) and $1,843,400 (.46 × .395 × $10,145,300).

4. Expected Cost of Additional Restrictions for the EPA79 Form

The cost savings analyzed here are the costs of actions taken by submitters as a result of the PMN process. As discussed in Chapter III, Section E, these actions include toxicological testing, withdrawal, labeling, development of a Material Safety Data Sheet, and reformulation.

To ensure consistency with the rest of the reporting rule analysis, the sample of approximately 500 notices developed by ICF is used in this analysis. As a result of the PMN process, one or more of the above-mentioned actions was taken for 2.3 percent of the substances in the sample. This translates to 20 chemicals, based on an annual submission rate of 900 chemicals. Based on the mix of actions required of actual PMNs, seven toxicity tests (four skin irritation, three skin sensitization), seven withdrawals, four labels, four material safety data sheets, and one reformulation would result. (More than one action has been taken in some cases.)[18]

Costs of the acute toxicology tests in 1979 dollars are $200-$1,000 for skin irritation tests and $400-$10,000 for the skin sensitization tests (Enviro Control 1980).[19] To update these estimates to account for inflation since 1979, the yearly inflation rate of 12.5 percent is used. This inflation rate implies that toxicological testing costs should have increased by 26.6 percent between 1979 and 1981, making the costs $253-$1266 for the skin irritation test and $506-$12,660 for the skin sensitization test in 1981 dollars.

Using the $371,700 to $560,400 range estimate of the lost profits per innovation (see Chapter III) we find that seven *withdrawals* could cost industry $2,601,900 to $3,992,800 annually. Even though we use these numbers here, it is important to recognize that the 90 percent confidence interval about the $438,500 estimate is from $0 to close to $1,500,000. Unfortunately it is not possible to estimate the uncertainty surrounding the $560,400 estimate.

The substance(s) for which *labels* were developed typically were small volume products. Maximum projected production volume was 40 pounds in the first year, 50 pounds in the second, and 60 pounds in the third. The substances were shipped in solution, at a concentration of 0.1 percent. Assuming that the solution weighs 8 pounds per gallon, 91 drums would be shipped in the first year, 114 the second year, and 136 the third year for each chemical requiring labeling. Because the actual costs of labels are approximately 2 cents per label, the cost of labels for all of these drums is only $2 the first year, $3 the second year, and $3 the third year. The cost of making the plates for the label, adjusted for inflation, is $135-506 (ICF (n.d.)). Therefore, the total direct cost per labeled PMN equals $137-$508 the first year, $3 the second year, and $3 the third year. Assuming that production continues at the third year rate for the indefinite future, that the price of labeling increases at the general rate of inflation, and that the "real" discount rate equals 10 percent, the present discounted values of direct labeling equals $192-$563 per chemical. However, it should be remembered that indirect economic effects such as reduced demand may result from the labeling requirement. Although these are certainly important, they are not addressed in this analysis of the direct costs associated with the PMN effect.

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[18] Often a MSDS and a label were requested. Occasionally, a label and a test were sought.

[19] The cost ranges given here are the low and high quotations from a survey of 12 testing labs.

Costs for material safety data sheets (MSDS) can be estimated from previous analyses. Based on a draft regulatory impact analysis done for OSHA, an MSDS has been estimated to cost $21.20 (OSHA 1982).

Reformulations can cost almost nothing; or they can cost thousands of dollars. Because there is a high variance associated with the cost of reformulation, a "mean" value would be misleading, and since we anticipate only one reformulation per year, we have not costed them here.

In summary, under the EPA79 form 20 chemicals can be expected to be affected annually. As shown in Exhibit IV-4 the total annual cost of these actions would be $3,072,882-4,038,180.

EXHIBIT IV-4

ANNUAL COSTS OF ACTIONS
(1981 Dollars)

Number & Type	Unit Cost	Total Cost
4 Skin Irritation	$253 - $1,266	$1,012 - $5,064
3 Skin Sensitization	$506 - $12,660	$1,518 - $37,980
7 withdrawn	$371,700 - $560,400	$2,601,900 - $3,992,800
4 Labels	$192 - $563	$768 - $2,252
4 MSDS	$21	$84
1 Reformulation	N/A	N/A
Total		$2,605,291 - $4,038,180

5. Summary Cost of EPA79 Form

The total annual industry cost of the EPA79 form is the sum of the four elements discussed above. Exhibit IV-5 shows that the total cost of the EPA79 form is at least $6.9 million to $20.6 million. If the non-quantifiable costs (cost of withdrawn PMNs, fears of confidentiality leaks, and costs of reformulation) were added to this, the costs would be even greater.

EXHIBIT IV-5

TOTAL ANNUAL INDUSTRY COST OF EPA79 FORM
(Thousands of 1981 Dollars)

Form Filing	$1,620 - $13,140
Confidentiality	$1,580 - $1,580
Delay	$1,055 - $1,843
Restrictive Actions	$2,605 - $4,038
Total	$6,860 - $20,601

C. ANALYSIS OF COSTS OF THE CMA79 FORM

The Chemical Manufacturers Association has developed a proposed PMN form based on the principle that section 5(a)(1) of TSCA provides an all-inclusive list of the information that a PMN is to contain (CMA 1979, p. 260). This form contains mandatory and optional parts. Mandatory parts include submitter's identity, chemical identity, production and use data, Federal Register notice, list of health and environmental data, and information in the submitter's possession regarding industrial sites not controlled by the submitter. Optional parts include risk assessment information (risk analysis, related chemicals, general industrial hygiene program, specific safeguards, process chemistry, transport data, and additional risk-relevant information) and additional information on work exposure and environmental releases.

1. Differences Between EPA79 Form and CMA79 Form

Differences between the EPA79 form and the CMA79 form are briefly explained below. These differences are examined more fully in Appendix D, which compares all three proposed reporting options.

a. Submitter's Identification.

The CMA79 form identifies the submitting company and the technical contact. However, it does not require identification of the parent company, expected manufacture commencement date, or prenotice communication information.

b. Identity.

The CMA79 form requires virtually the same information as the EPA79 form with two exceptions: no minimum average molecular weight is required for polymers and no information on approaches to controlling the concentration of impurities is required (although the maximum concentration of impurities is required).

c. Production and Marketing Data.

The CMA79 form requires estimates of the first three years typical production volume; but unlike the EPA79, does not require maximum and minimum estimates. Use data would be somewhat simplified, with requirements only for identification of use categories and the percentage of anticipated annual production which would be devoted to each use category. No further breakdowns by function or application would be required. Information on whether the substance has been manufactured before would be optional, as would be the requirement to provide a copy of a hazard warning (if any). Information on the number of customers committed to purchase and the percent of production involved would not be required.

d. Other General Information.

Under the CMA79 form, information on transport, risk assessment, and detection methods is optional.

e. Industrial Sites Controlled by Submitter.

The CMA79 form requires identity of the site of manufacture. It does not require specification of the site type or a block diagram. Information on hours operated and amount manufactured, processed, or used would be optional. Required occupational exposure includes number of workers exposed, the route of exposure, and identification of other substances to which workers may be exposed. More detailed information about the specific operations where exposure could take place or physical states of the substance during exposure would not be required.

Required environmental release and disposal information would include identification of method of disposal, and indication of "minimal" release quantities where appropriate. CAS Registry numbers of byproducts would also be required. However, all other information on environmental release and disposal would be optional.

f. Industrial Site Controlled by Others.

The CMA79 form contains no mandatory customer contact provisions. However, based on data already in the submitter's possession, the submitter would be required to provide the same types of information about sites controlled by others as for the submitter's own sites.

g. Consumer and Commercial User Exposure.

Under the CMA79 form, almost all information on consumer and commercial work exposure would be optional. Information on byproducts formed from each category of use would not be required.

h. List of Attachments and Federal Register Notice.

Data on physical/chemical properties would not be required. A Federal Register notice would be required, but it would not include the identity of the manufacturer.

As this content comparison shows the CMA proposal contained considerably less mandatory information than the EPA79 form, and its cost is lower as well.

2. Form-Filing Costs of the CMA Proposal

Appendix G includes is a copy of the CMA79 form. Its cost is estimated by ICF to be between $1,300-$6,400 for mandatory information. Exhibit IV-6 shows the ICF estimate of hours required for each section. A complete analysis of this form can be found in ICF's report to EPA "Estimated Costs to Complete the CMA Proposed Form," July 1981. Assuming 900 PMNs annually, total form filing costs are $1,170,000 to $5,760,000.

3. Confidentiality Costs of CMA Proposal

The EPA79 form required that all substantiation of confidential claims must be provided with the initial submission. However, the CMA79 form call for substantiation of confidential claims only when an FOIA request is

EXHIBIT IV-6

ESTIMATED LABOR REQUIREMENTS FOR CMA79 FORM

PART OF FORM	TECHNICAL	MANAGERIAL
I. General Information		
A. Submitter Identity	0-0	1-8[1]
B. Chemical Identity		
1. Class I Chemical Substance	1-4	0-0
2. Class II Chemical Substance	1-4	0-0
3. Polymers	1-4	0-0
4. Impurities	1-6	0-0
5. Chemical Identity Claimed Confidential	0-4	0-1
C. Production and Categories of Use Information		1-2
1. Production Volume	1-3	
2. Production by Use Category	1-5	
D. Federal Register Notice	1-4	0-1
E. List of Attachments	0-1	0-0
II. Risk Assessment Data		
A. Chemical Properties, Environmental Characteristics, and Human and Ecological Effects Data		
1. Test Data on Physical/ Chemical Properties	4-16	1-4
2. Test Data on Health and Environmental Effects	8-40	2-8
B. Occupational Exposure, Disposal, By-Products		1-2
1. Industrial Sites Controlled by the Submitter		
a. Occupational Exposure	1-4	
b. Disposal of Chemical Substance	1-4	
c. By-Products	0-3	

EXHIBIT IV-6 (continued)

ESTIMATED LABOR REQUIREMENTS FOR CMA79 FORM

PART OF FORM	TECHNICAL	MANAGERIAL
2. Industrial Sites Not Controlled by Submitter		
a. Workplace Exposure	0-4	
b. Disposal of Chemical Substance	0-4	
Subtotal--Mandatory Portion a/	21-102	6-26
Plus Clerical Hours:	6-17	

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a/Includes legal review and final managerial sign-off.

filed (except for generic masking of chemical identity). Therefore, the total cost of submission depends on the frequency with which FOIA requests are filed. An examination of the record of FOIA requests reveals that FOIA requests were made on 17.7 percent of a sample of notices from 1981. Therefore, it is assumed that substantiation will be required for 17.7 percent of all notices submitted. Because almost all the FOIA requests were filed within 6 months after the submission of the notice, it is assumed that costs of substantiation do not increase between the time of submission and the time of the FOIA request.

Not all of the cost of substantiation is delayed until an FOIA request is made, however. With the CMA79 form, a single generic chemical identity plus a generic use is required, and under this option a single generic chemical use is assumed for purpose of the analysis. We estimate that the cost of developing one generic chemical identity is $80, and the cost of developing a generic use is $28.[20] Chemical identity is claimed confidential and a generic name is required for 70 percent of the notices in the ICF sample. "Use" is claimed confidential in 45 percent of the ICF sample. Therefore, the cost per submission of providing a generic name is $56 ($80 × .7), and the expected cost of providing a generic use is $13 ($28 × .45). Because the total expected cost of confidentiality per submission is $1755, the expected confidentiality costs less these two items is $1686 ($1755 less $69).

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[20] In our analysis of the cost of the EPA79 form, we determined that completing the proportion of the form that called for the provision of up to three generic chemical identities would take 0-4 technical hours and 0-1 managerial hours. It is assumed that provision of three generic names would take the maximum amount of time, and that provision of one generic name would take one-third of the maximum time estimate. The cost of providing a generic use was not previously estimated by ICF. The estimate used here was based on a comparison of the difficulty of deriving a generic use to the difficulty of deriving a generic name.

The CMA79 form requires that a generic name for the PMN substance be provided at the time of submission, and the rest must be provided only if an FOIA request is made. In other words, an expected cost of $56 is incurred at the time of submission, and a cost of $1699 is incurred 17.7 percent of the time. Therefore, expected confidentiality costs per submission equal $357. For 900 PMNs, total cost is $321,300.

Disclosure of trade secrets and uncertainty would be very small under this option and no different from the EPA79 form.

4. Delay

Delay costs would not change with the CMA79 form. Like the EPA79 proposal, delay costs would range from $1,054,500 to $1,843,400.

5. Restrictive EPA Actions

Analysis led to the conclusion that there would probably be a change in the number of PMNs "caught" (i.e., subjected to one or more actions to protect human health or the environment) if the CMA79 form was used. The cost would be from $2,308,000 to 3,578,000 annually. This result is based on the information shown in Exhibit VII-2; adjusting the EPA79 restrictive action costs to reflect the probability of actions being taken using the CMA79 form.

6. Summary

Total annual costs to industry of the CMA79 form are shown below in Exhibit IV-7.

EXHIBIT IV-7

TOTAL ANNUAL COSTS OF THE CMA79 FORM
(1981 Dollars)

Cost of Forms	$1,170,000	-	$ 5,760,000
Confidentiality	$321,000		$321,000
Delay	1,055,000	-	$1,843,000
Restrictive Actions	$2,308,000	-	$3,578,000
Total	$4,854,000	-	$11,502,000

D. ANALYSIS OF COSTS OF THE EPA82 FORM

The information sought under this proposed form includes: submitter's identity; chemical name; identity and molecular structure; simplified production and marketing data; simplified flow diagram; and simplified worker exposure, release, and disposal estimates (relative to the EPA79 form).

1. Differences Between the EPA82 Form and EPA79 Form

Differences between the EPA82 form and the EPA79 form are explained below. These differences are highlighted in Appendix D.

a. Submitter's Information.

The EPA82 form would require the same information as the EPA79 form except that the parent company and expected manufacture commencement date are not required.

b. Chemical Identity.

The EPA82 form would require basically the same information as the EPA79 form, with the addition of molecular weight distribution and distribution of low-weight species.

c. Production and Marketing Data.

EPA would not request maximum and minimum production volumes for each of the first three years of production. Estimates of the number of customers for each category of use and descriptions of categories not contributing to production estimates but actively explored would not be required. These changes reduce the information reported to what is needed to identify specific information requirements for detailed review.

d. Other General Information.

Sections on transport methods and detection methods would be eliminated since they are rarely used even for detailed review. Space for providing a risk assessment would be eliminated since EPA interprets this as a health and safety study which would be received as part of test data.

e. Industrial Sites Controlled by Submitter.

EPA would not require identity of site, amount manufactured or processed, reactions and side reactions for each chemical conversion, identification and weight of all materials entering and leaving each operation and conversion, methods of transfer, whether system is open or closed to the workplace, or points of release of the new substances or byproducts. Such information would be requested for detailed review, if needed.

EPA would not require submitters to identify operations in which workers may be exposed and routes of exposure. Such information can be derived from the flow diagram and professional judgment. EPA would also not require identity of site, estimates of materials entering and leaving each operation and conversion, methods of transfer, whether system is open or closed, or points of release of the new substances or byproducts. Such information may only be needed for detailed review.

Also a list of substances, other than the new substance, that are likely to occur in the workplace would not be required. This information would be requested during detailed review, if needed.

For releases, EPA would not require identity of site, estimates of the amount of new substance released, or effluent stream flow rate.

Thus, the required information for sites controlled by the submitter includes: (1) process information on site type and hours operated; (2) process description; (3) number of employees exposed, duration and route of exposure, and physical states during exposure; and (4) duration and control approaches for environmental releases.

f. Industrial Sites Controlled by Others.

The new form would not contain customer contact provisions and no information on industrial sites controlled by others would be requested for initial review.

g. Consumer and Commercial User Exposure.

No consumer and commercial user exposure information would be required, but the submitter would have the option of providing demographic data.

h. List of Attachments and Federal Register Notice.

No data on physical/chemical properties would be required. However, other requirements for notice attachments remain as under the EPA79 form. A Federal Register notice would not be required.

2. Form-Filing Costs for the EPA82 Form

The EPA82 form represents a decrease in hours and costs from previous proposals. Using the labor rates discussed in Chapter III and hours estimates derived from the estimates of the labor hours necessary to complete the EPA79 form as shown in Exhibit IV-8, it should cost between $1,200 and $6,200 to complete all mandatory sections of the EPA82 form. Assuming 900 PMNs per year, the total annual cost of the mandatory portion is $1,080,000-5,580,000.

The differences between the EPA82 form and the EPA79 form are mostly deletions. The EPA79 form requests information on chemical identity, production and marketing plans, transport, risk, detection methods, exposure and release at sites controlled by the submitter, exposure and release at sites controlled by others, consumer and commercial exposures, a Federal Register Notice and attachments. The EPA82 form deleted the transport, risk,

EXHIBIT IV-8

ESTIMATED LABOR REQUIREMENTS FOR EPA82

		CLERICAL	TECHNICAL	MANAGERIAL
I.	General Information	2-6		
A.	Submitter Identification			1-8[2]
B.	Chemical Identity			
1.	Class 1 or 2		1-4[3]	
2.	Polymers		1-6[3]	
3.	Impurities		1-6	
4.	Trade Identification		0-1	
C.	Generic Names		0-4	0-1
D.	Production and Marketing Data			1-2
1.	Production Volume		1-4	
2.	Category of Use		1-8	
3.	Hazard Information		1-1	
II.	Human Exposure and Environmental Release	2-5		
A.	Industrial Sites Controlled by the Submitter			2-6
1.	Operations description			
	- type and duration		1-2	
	- block diagram		1-12	
2.	Occupational exposure		1-8	
3.	Environmental release		1-6	
IV.	List of Attachments	2-6		
V.	Test Data			
A.	Notice Form Sections[1]		--	
B.	Environmental Fate data		8-40	2-8
C.	Health and Environmental Effects Data			
TOTAL		6-17	17-98[4]	6-25

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[1] Included in above estimates.
[2] Included legal review time.
[3] Only one of these two sections would be completed.
[4] Counts polymer chemical identity section, not Class 1 or 2.

detection methods, exposure and release at sites controlled by others, consumer and commercial exposure, and Federal Register Notice requirements. In addition it simplified the production and marketing, exposure and release, and attachments section. The only additional request was for molecular weight distribution data for polymers. Exhibit IV-8 summarizes the hour estimates for the mandatory portion of the EPA82 form.

3. Confidentiality Cost for the Proposed EPA82 Requirements

EPA82 requires generic chemical identity and generic chemical use although substantiation is not required for these items. The costs to provide these items were previously estimated as $56 and $13 per PMN respectively. Substantiation of confidentiality claims only occurs when an FOIA request is made.

In other words, an expected cost of $69 is always being incurred. Since FOIA requests occur 17.7 percent of the time, other confidentiality costs of $1686 ($1755 less $69), occur that often for a total of $298 per submission ($1686 x .177) on average. Therefore, confidentiality costs per submission equal $367 ($69 + $298). For 900 PMNs, total annual confidentiality costs for the final form are $330,300.

4. Delay Cost for the EPA82 Form

Delay costs are the same for this option as for other options. As before they range from $1,054,500 to $1,843,400.

5. Costs of Restrictive Actions for the EPA82 Form

EPA analysts have determined that the number of restrictive actions will differ with alternative forms. Therefore, costs of restrictive actions are $2,373,000 to $3,679,000 based on the probability of health or environmental problems being caught by the EPA82 form compared to the EPA79 form.

6. Summary of Costs for the EPA82 Form

Exhibit IV-9 provides the costs estimates for the proposed EPA82 form.

EXHIBIT IV-9

TOTAL ANNUAL COSTS OF THE EPA82 FORM
(Thousand of1981 Dollars)

Cost of Forms	$1,080 - $5,580
Confidentiality	$330 - $330
Delay	$1,055 - $1,843
Restrictive Actions	$2,373 - $3,679
Total Costs	$4,838 - $11,432

E. COMPARISON OF COSTS OF THE ALTERNATIVES

In the previous three subsections, the quantifiable costs of each alternative were developed. In this subsection the totals are compared. EPA79 is more expensive primarily because its mandatory form completion costs and confidentiality costs are higher than the others. The delay costs and restrictive action costs do not change among the alternatives. Exhibit IV-10 compares the options.

EXHIBIT IV-10

COMPARISION OF INDUSTRY COSTS OF ALTERNATIVES
(Millions of 1981 Dollars)

	Total Annual Cost	Savings Over EPA79 Form
EPA79 Form	$6.9 - 20.6	— —
CMA Proposal	$4.8 - 11.5	30% - 44%
EPA82 Form	$4.8 - 11.4	30% - 45%

F. EFFECT OF PROPOSED EXEMPTIONS PROGRAM ON SECTION 5 PROGRAM COSTS

This subsection discusses the effect of exemptions on the costs estimated in the previous subsections. Under current or proposed exemption rules, the following four categories of chemicals would be eligible for some sort of exemption from the regular PMN process: low volume chemicals (proposed rule), site-limited intermediates (proposed), instant photographic chemicals (final rule), and polymers (proposed). Some new chemicals are likely to be eligible for more than one exemption. For example, a new polymer might be produced at low levels, thus making it potentially eligible for both the polymer and low volume exemptions. Or, companies intending to manufacture new site-limited intermediates would have the option of producing that chemical under one of the low volume exemptions as long as they were to be produced in quantities of 10,000 kg or less, and met the specific exemption terms applying to that category. The choice of which exemption to use for those chemicals eligible for multiple exemptions will be left to the manufacturer.

The chemicals to which each exemption applies, as well as the nature of the exemption, are enumerated below:

- Low Volume Exemptions. Prior to commencement of manufacture, the submitter must submit a short exemption notice (containing the manufacturer's name, manufacturing site, the chemical identity of the compound, its use.) Except for chemicals manufactured at volumes less than or equal to 1,000 kg a year, the chemical must be reviewed by a qualified expert employed by the submitter. Carcinogens, teratogens and acutely toxic chemicals would be automatically excluded. For chemicals with a production volume less than 1,000 kg/year, this review need not be performed. EPA must review exemption requests within 14 days.

For the 1,000 kg or less exemption, there are no automatic exclusions from the exemption. If the chemical substance has serious acute or chronic effects or significant environmental effects under conditions of use it is excluded from the exemption.

EPA would have the authority to declare a specific chemical ineligible for the exemption if it failed to meet the terms of the exemption. The rule would also establish procedures by which EPA could revoke exemptions for chemicals found to be ineligible for exemption after manufacture had commenced.

- Site-Limited Intermediates. This exemption is similar to the low volume exemption. Site-limited intermediate chemicals would be automatically excluded from the site-limited intermediate exemption if they had carcinogenic or teratogenic effects. Site-limited intermediate chemicals would also be excluded from the exemption (based on conditions of use) if they had serious acute or chronic effects, or significant environmental effects. Manufacturers must submit a short exemption notice. Again, EPA has 14 days to act on exemption requests.

  EPA would have the authority to declare a specific chemical ineligible for the exemption if it failed to meet the terms of the exemption. The rule would also establish procedures by which EPA could revoke exemptions for chemicals found to be ineligible for exemption after manufacture had commenced.

- Polymers. Under this exemption, polymers would be potentially eligible for an exemption from PMN requirements if they were not specifically excluded from the exemption, and met certain eligibility criteria. In addition, certain procedural and other safeguards would be imposed. The basic elements of this alternative are as follows:

a) Certain polymers would be automatically excluded from the exemption. These would include water soluble polymers, biopolymers, polymers that exceeded specified content levels for certain elements, polymers with covalently bonded halogen or cyano groups, polymers with certain reactive functional groups, and polymers designed to degrade, decompose, or depolymerize.

b) Polyesters which are made from a specified list of monomers would be eligible for the exemption if manufacturers notified EPA when they begin manufacture of the new polymer. Residual content of certain listed monomers would be limited to one percent.

c) Polymers that met certain number-average molecular weight and polydispersity criteria would be exempt if the manufacturer notified EPA when manufacture of the new polymer commenced. The notice would include chemical identity and reasonable estimates of polydispersity and average weight as defined in the proposed rule.

d) Polymers above 1,000 number-average molecular weight would be eligible for an exemption if manufacturers notified EPA at least 14 days before they produced the chemicals. The notice would include chemical identity information, residual content, production volume, and a description of use.

e) EPA would have the authority to declare a specific chemical ineligible for the exemption if it failed to meet the terms of the exemption. The rule would also establish procedures by which EPA could take regulatory action, or require that a PMN be filed for a specific chemical, if it determined that serious unresolved issues concerning toxicity or exposure remain at the end of the 14-day period, or if the

Agency at any time, determined that the manufacture, processing, use, or disposal of the polymer may present an unreasonable risk.

- Instant Photographic and Peel-Apart Film Articles. This exemption applies to chemicals used as ingredients in "instant" photographic and peel-apart film. Under this exemption, already in force, manufacturers (primarily, Polaroid and Kodak) are allowed merely to submit notification of intent to begin manufacture on or before the first day of production. They must certify that they are aware of the exposure and environmental release provisions of the exemption (an exposure limit of 10 ppm or 50 $\mu g/m^3$, engineering controls and personal protective devices, water and air effluent treatment guidelines) and are willing to abide by them.

1. Cost of Exemption Notices

The exemptions being proposed by EPA require that manufacturers of exempted chemicals provide notices of intent to manufacture. EPA estimated the cost of all the exemption notices except for the photographic chemicals notice. We assume that the photographic exemption notices will cost the same as the least expensive exemption notice.

Notices for low volume chemicals and site limited intermediates would be required to include certain information on chemical identity, site of manufacture, production volume, and use. If a chemical is to be produced in quantities between 1,000 and 10,000 kilograms per year or is a site-limited intermediate then a qualified expert must evaluate the chemical. Both of the low volume exemptions and the site-limited intermediate exemption are 14-day premanufacture notices. This means the manufacturer must wait 14 days before commencing production. The polymer exemption calls for zero-day notice for some polymers and a 14-day premanufacture notice for others. The instant photographic exemption is a zero-day premanufacture notice with certification that proper exposure and release provisions will be followed.

ICF and EPA estimated the cost of a risk assessment by a qualified expert to be \$695-\$1,575 if exposure was limited (Warhit 1982 Appendix B). In cases where exposure was expected to be more widespread, the cost would be \$1,195-\$3,075 (Warhit 1982 Appendix B). Both of these estimates were based on October 1980 labor rates. Using December 1981 labor rates would result in the costs rising to \$790-\$1,780 for the limited exposure analysis and \$1,340-\$3,440 for the full risk and exposure assessment.

The cost of an exemption notice for the low volume, 14-day review polymers, and site-limited chemicals was estimated using October 1980 labor rates to cost from \$150-\$420 assuming no risk assessment was required (Ng 1982, p. 76). For polymers, the zero-day notice should cost \$190-350 (Luttner 1982, p. 106). Using December 1981 labor rates, these costs would rise to \$170-\$480 for the low volume, polymer 14-day, and site-limited notices; and \$210-\$370 for the polymer zero-day notice. Exhibit IV-11 summarizes the cost of each notice.

EXHIBIT IV-11
COST OF EXEMPTION NOTICE[21]
(1981 Dollars)

Exemption Notices	
Less than 1,000 Low Volume	\$170- 480
Other Low Volume	\$960-2,260*
Site-Limited	\$960-2,260
Photographic	\$170- 480
Polymer Zero-Day	\$210- 370
Polymer 14-Day	\$170- 480

* Could be as high as \$1,510-\$3,920 if exposure was not limited.

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[21] Values derived from EPA exemption analyses adjusted for inflation in labor costs to move forward to December 1981.

2. Total Annual Cost of Exemption Alternatives

In order to estimate the total annual cost of the alternatives, the number of notices required must be computed. In a previous analysis (Luttner and Shapiro 1982), EPA estimated that, without exemptions, 900 PMNs would be submitted annually. This estimate (900 PMNs per year) has been used to compute costs of the reporting alternatives without exemptions.

To determine the number of PMNs that would be exempted we analyzed a data base of about 500 PMNs considered representative of all 1,700 submitted to date. Based on this analysis we determined the percentage of chemicals annually falling into different exemption categories. We multiplied the percentages by 900 to obtain numbers of exemptions. Our derivation of the number of and kinds of exemptions expected annually is explained below.

When the individual exemption alternatives are considered separately the following results are obtained:

- 39 percent of PMNs qualify for the low volume exemption with 52 percent of these qualifying for the less than 1,000 kg notice and 48 percent qualifying for the greater than 1,000 kg notice;
- 10 percent of PMNs are site-limited intermediates of which 75 percent would qualify for exemption;
- 3 percent of PMNs qualify for the instant photographic exemption;
- 26 percent of PMNs qualify for exemption as polymers.

Together these percentages sum to 75.5 percent. However, considerable overlap among exemptions exists. About one-half of the eligible site-limited intermediate are also low volume, and 20 percent of the polymers are low volume. Thus, when all exemptions are considered as a package, only 64 percent of the PMNs in this sample would be exempted.

The precision of the exemption percentage estimates is not exact. They should be viewed as ranges of plus or minus five to ten percent. The lack of precision stems from the changing nature of the PMN chemical submissions. Over time the types of chemicals being submitted under the PMN process will change as will the number of PMNs. The PMN sample used to determine the exemption percentage estimates is thought to be indicative of the steady state of PMN submissions during the 1980-1982 period, but a different sample would provide slightly different estimates. Therefore these estimates should not be taken as exact percentages but rather as approximate percentages.

In this analysis, we assume that a submitter whose chemical qualifies for any of several exemptions will choose to file an exemption under the alternative with the lowest filing cost. Thus, many of the site-limited intermediates with production volumes less than 1,000 kg per year were assumed to be produced under a low volume exemption. If they expect production volumes greater than 1,000 kilograms, they would choose to avoid the later year reporting requirements that occur when production exceeds certain limits by filing under the site-limited intermediate exemption. Likewise, submitters for polymers are assumed to file the polymer exemption no matter what their production volume. Out of those that would be exempt, data analysis revealed that 24 percent would submit less than 1,000 kg low volume exemption notices, 25 percent 14-day low volume exemptions notices; 6 percent site-limited intermediate exemption notices; 5 percent instant photographic exemption notices; and 40 percent polymer exemption notices. According to analysis of our data base, the polymer notices would be split 51 percent zero-day polymer notices and 49 percent 14-day polymer notices. Overall, the Agency would receive about 576 exemption notices annually. Exhibit IV-12 shows the number of each kind of notice the Agency would receive under each alternative.

Using the counts from Exhibit IV-12 and the cost per notice from Exhibit IV-11, we can compute the total annual cost of exemption notices as shown in Exhibit IV-13.

EXHIBIT IV-12

NUMBER OF NOTICES RECEIVED ANNUALLY*

	No Exemption Policy	Proposed or Current Exemption Policy
PMNs	900	324
Less than 1,000 kg Low Volume		138
Over 1,000 kg Low Volume		144
Site-Limited Intermediate		35
Instant Photographic		29
Polymer Zero-day		117
Polymer 14-day		113
Total	900	900

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*This analysis assumes that PMN costs have had no effect on numbers of new chemicals introduced.

EXHIBIT IV-13

ANNUAL FORM-FILING COST OF EPA82 FORM WITH AND WITHOUT EXEMPTIONS

(Thousand of 1981 Dollars)

With No Exemption	$1,080 - $5,580
With Proposed and Final Exemptions	$633 - $2,590
Difference	$447 - $2,990

3. Exemption Options and Delay Costs

The exemptions will affect delay costs because chemicals which are exempt will be subject to less pre-submission and post-submission delay. Pre-submission delay will be reduced under the proposed exemptions because the time required to complete an exemption notice will be reduced. Although no hard data exist with which to estimate pre-submission delay under the proposed exemptions, it would seem that in most cases the pre-submission delay period should not exceed one week.[22] Therefore, for purposes of this analysis, it will be assumed that the pre-submission delay period for chemicals covered by the exemption will be equal to one week.

Post-submission delay will be reduced under the proposed exemption policy because some chemicals now subject to ninety-day review periods would be only subject to zero-day or fourteen-day reviews. Most chemicals eligible for exemptions will be subject to fourteen-day review. However, some polymers and all instant photographic chemicals will be subject to zero-day review.

In order to estimate the proportion of PMN submissions eligible for exemption, the sample of approximately 500 chemicals was analyzed. It was found that 64 percent would only be eligible for exemptions, as discussed previously. Based on an annual PMN submission rate of 900 chemicals, this would result in 576 chemicals eligible for exemptions.

For the 576 chemicals expected to benefit from delay reductions under the proposed exemptions, analysis revealed that 24 percent (144) would be eligible for the zero-day review period while 75 percent (432) would be eligible for the fourteen-day review period. Thus total delay for 144 would be 7 days; and for 432, 21 days. Chemicals eligible for zero-day review include instant photographic chemicals and certain polymers (about 50 percent of eligible polymers). Chemicals eligible for fourteen-day review include other polymers, site-limited intermediates, and low volume chemicals. For the 324 still submitting PMNs, 321 would experience 120-day delays and 3 would experience 210-day delays. Total delay costs then would be 0.1% × 144 × .46 × $438,500; plus .3% × 432 × .46 × $438,500; plus 1.6% × 321 × 46 × $438,500, plus 2.8% × 3 × .46 × 438,500 (assuming a 5 percent real rate of return). This totals $1,343,400. At a 10 percent real rate of return the total delay costs would be $2,364,400 if all PMNs were subject to delay. However, only 39.5 percent (those with COMs within 30 days) may be subject to delay. Thus estimated delay cost are $530,600 to $933,900 (See Section C, Chapter III for details.)

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[22] The only situation in which delay might exceed one week would be one in which a risk assessment required extensive data gathering from sources not quickly accessible to the submitter. This would only occur for site-limited intermediate and 1,000-10,000 kilogram low volume exemption candidates. Together these represent only 26.5% of all chemicals eligible for exemption.

Exhibit IV-14 provides a comparison of delay costs with and without the exemption rules.

EXHIBIT IV-14

ANNUAL DELAY COSTS WITH AND WITHOUT SECTION 5 EXEMPTIONS

(Thousands of 1981 Dollars)

No Exemptions	$1,055 - $1,843
Proposed Exemptions	$ 531 - $ 934
Difference	$524 - $909

4. Effect of Exemptions on Confidentiality and Restrictive Actions

Exemptions will not affect confidentiality costs because confidentiality provisions for exemptions notices will be identical to those for the EPA82 form. The marginal cost of asserting confidentiality is close to zero. In cases where substantiation is later required there is no data to suggest that providing substantiation for several items (on the EPA82 form) is more costly than providing it for a few (on exemption notices). (Although it might intuitively seem more costly; most substantiations in PMN files appear to be boiler plate language).

5. Cost Savings From Exemptions

Overall the exemption program would save industry from $1.0 to $3.7 million annually.

G. COST TO GOVERNMENT

The cost to EPA to review the alternative forms does not change significantly among them for several reasons. First of all, the experience to date indicates that even for the standard EPA79 form, tremendous variation in the quality and amount of information provided exists. Thus, the Agency in its initial review process often relies on telephone conversations with companies to fill in data gaps. In addition, some of the information with which the Agency has been provided is not essential to the initial review. The Agency has learned through its review of over 1,700 PMNs which items are critical for initial review. All three forms usually have this information. Whenever a company does not submit these items, the Agency typically calls the company for the information. The phone calls do not in our judgement add substantially to the cost estimates developed in Chapter III. Therefore, ICF does not believe the Agency costs will change with the choice of forms. Assuming 900 PMNs per year, total costs will be 900 x $7,728 (from Chapter III) or about $6,955,200 annually.

Implementation of exemptions, however, will significantly change EPA costs. The savings can be calculated using a three-step process. First, it is necessary to determine how many PMNs would no longer be submitted because the chemicals in question qualified for exemptions. This number must be multiplied by the cost to review these kinds of PMNs. Next, it is necessary to determine what kinds of exemption notices would be submitted. These must be multiplied by the cost to review exemption notices developed in Chapter III. These exemption notice review costs must then be subtracted from the savings from not performing PMN reviews.

The exemption program will reduce the number of PMNs EPA must review annually by 576 (assuming 900 are received). Instead it will process:

- 138 less than 1,000 kg low volume exemption notices at a cost of $640 per notice
- 144 14-day low volume exemption notices at a cost of $1,483 per notice
- 35 site-limited intermediate exemption notices at a cost of $1,483 per notice
- 29 instant photographic exemption notices at a cost of $640 per notice
- 117 zero-day polymer exemptions at a cost of $640 per notice
- 114 14-day polymer exemptions at a cost of $1,483 per notice

Because the exemptions are designed to exempt only those chemicals that do not represent an unreasonable risk to health or the environment, we can assume that the submitters of the types of chemicals presently undergoing detailed review and section 5 control actions will continue to submit PMNs. We can also assume that the chemicals for which manufacturers submit exemption notices will be among the 95 percent of all PMNs that only went through initial review and were dropped. The savings from not reviewing 576 "typical" PMNs is then 576 times $4,593 (see Exhibit III-5) or $2,645,568. The cost to review 576 exemption notices with the mix of characteristics shown is $616,279. Therefore, the savings to government from the exemption program is $2,645,568 less $616,279 or $2,029,289.

H. OTHER COSTS

This chapter has provided estimates of the direct costs of compliance for regulated parties and government. These direct costs represent the expenditure of resources by regulated parties and governments that is required for compliance with the section 5 regulations. These direct costs, however, are only part of the total costs to society. This section briefly discusses the other components of total cost to society.

1. Indirect Costs

In addition to direct costs, indirect costs may also be incurred by regulated parties and governments. These indirect costs represent the expenditure of resources by regulated parties and governments that is induced, though not required, by the section 5 regulations. One type of indirect cost is toxicological testing. Although no toxicological testing is specifically required under section 5, regulated parties may choose to test in order to increase the probability that production of their new chemicals will not be regulated by EPA. Another example of induced costs are the costs of reduced innovation. The innovation effects of section 5 regulation are discussed in more detail in Chapter V.

The expenditures of resources by regulated parties and governments caused both indirectly and directly by section 5 may have further effects throughout the economy. The expenditure of resources by regulated parties may affect their output, the prices at which they sell their output, their profits, and the number of workers they employ. Changes in the price and output decisions of individual firms may produce industry-wide changes in prices, output, and profits, and may spread to other industries and the U.S. economy as a whole. The costs incurred by government may result in some combination of higher taxes, higher government borrowing, and reductions in spending on other EPA programs.

The ultimate measure of the cost to society of all these effects is the value of goods and services lost by society as a result of the use of resources to comply with a regulation, and the use of resources to implement a regulation. The cost to society can be represented by changes in the difference between the price of a good and the amount that consumers are willing to pay for it. In a competitive market, all consumers pay the same price, i.e., the price established by the interplay of supply and demand. However, there generally are some consumers who would purchase the product if it were offered at a higher price. These consumers receive a bonus or consumer surplus.[23] If section 5 regulation raises the price of new chemicals, society will consume smaller quantities of them, thereby reducing consumer surplus. If section 5 regulation reduces the number of new chemicals introduced, consumers will not receive this bonus from the foregone new chemicals.

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[23] Another element of the cost of regulation is producer surplus, where this is defined as the profits above a fair return on capital earned from the development, commercialization and sale of goods and services. (It is also known as the return to entrepreneurship.) In a competitive environment, all producers receive the same price, and their combined supply curve includes a return on capital invested. However, there usually are producers who would be willing to offer their product at a lower price. These producers receive an extra profit or producer surplus. If regulations prevent introduction of a product, producers lose this producer surplus. However, the loss in producer surplus from a reduction in new product introduction is offset by a reduction in producers' research and development expenditures. Therefore, the total cost to society of section 5 regulation is measured by consumer surplus.

2. Distributional Costs

The distribution of cost among members of society must also be examined in evaluating the quality of the regulation. Regulations may affect different firms and industry segments in different ways. For example, a particular reporting requirement might place more of a burden on one particular industry segment that commonly introduces large numbers of chemicals, than on another segment of the industry which does not introduce new chemical products so frequently. It has been suggested, for example, that some small businesses may have stopped innovation activities because the costs of section 5 notices, as perceived by them were too onerous. These effects will be discussed further in Chapter VI.

I. CHAPTER SUMMARY

The form-filing, confidentiality, delay, and restrictive action costs of the regulatory options under consideration have been developed in this chapter. The EPA79 notice would cost industry between $6.9 and $19.0 million. The CMA79 notice would cost industry $4.8 to $11.5 million; and the least expensive EPA82 notice would cost between $4.8 and $11.4 million. EPA costs would be about $7.0 million annually.

With exemptions, the three alternative forms would cost industry and EPA the amounts shown in Exhibit IV-16. As the Exhibit shows industry costs drop from 20-34 percent when the EPA82 form is used, and EPA costs 29 percent.

EXHIBIT IV-15

DIRECT COSTS OF REGULATORY OPTIONS

(Thousands of 1981 Dollars)

	EPA79	CMA79	EPA82
Total Industry Costs			
Form Filing Costs	$1,620 - 13,140	$1,170 - 5,760	$1,080 - 5,580
Confidentiality Costs	1,580	321	330
Delay Costs	1,055 - 1,843	1,055 - 1,843	1,055 - 1,843
Restrictive Actions	2,605 - 4,038	2,308 - 3,578	2,373 - 3,679
Total	$6,860 -20,601	$4,854 -11,502	$4,838 -11,432
Total EPA Costs			
Review	$6,955	$6,955	$6,955
Total Costs	$13,815 -27,756	$11,809 -18,457	$11,793 -18,387

EXHIBIT IV-16

ANNUAL COSTS OF ALTERNATIVE FORMS WITH EXEMPTIONS IN PLACE

(Thousands of 1981 Dollars)

Form	Total Industry Costs	% Change*	Average Submitter Cost per New Chemical	EPA Costs	% Change*
EPA79	5,542 - 11,863	19 - 38	6.2 - 13.2	$4,935	(29.0)
CMA79	3,825 - 7,488	21 - 35	4.2 - 8.3	$4,935	(29.0)
EPA82	3,867 - 7,533	20 - 34	4.3 - 8.4	$4,935	(29.0)

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*Change relative to costs without exemptions.

CHAPTER V

INNOVATION EFFECTS

Many parties argue that the major economic effect of section 5 of TSCA will be changes in the innovation activities of chemical companies (CWPS 1981 CMA 1979, pp. 112-160, CMA 1981, Heiden and Pittaway 1982). For this reason it is appropriate to discuss the ways in which the PMN process affects innovation and to present some analyses of the possible magnitude of the effect.

Innovation activities encompass a large number of different efforts including process research and development, existing product research and development, new product research and development, and new chemical research and development. For purposes of this discussion, process research and development are those activities directed toward increasing efficiency by changing the technology used to produce an existing product. Existing product research and development are those activities directed toward making an already existing product better. Usually this means improving the quality of the product. New product research and development is directed toward the advancement of scientific knowledge and development of new products, as well as toward new technologies necessary to bring the product to market. New product R&D may include new formulations, significant new applications of existing chemicals, and, of course, the subject of this analysis, new chemicals. New chemical R&D, a subset of new product R&D, is those activities directed toward bringing to the market a totally new compound.

In this chapter we explore how the costs of filing a PMN (developed in Chapter IV) might affect new chemical research and development. Then previous analyses estimating the effect of PMN requirements on new chemical innovation are discussed and conclusions about the innovation impact drawn.

A. BACKGROUND

Previously ICF estimated that the effects of the section 5 program would be potentially noticeable at each step of the innovation process (ICF 1980, Part I, p. 83-110). These steps were defined as:

- Resource allocation to research and development;
- Allocation of research and development budget among process, existing product, new product, and new chemical activities;
- The creative research process;
- Commercial development; and
- Market introduction and response.

In the resource allocation decision, the existence of section 5 costs would potentially reduce the return available from research and development and therefore chemical companies might invest in other kinds of activities (e.g., capital or labor). At the allocation of the R&D budget stage, the company might choose to deemphasize new chemicals and new products in favor of new processes or it might cut basic research and focus on developmental activities. In the creative research process, management could stop all projects geared toward developing chemicals whose properties were similar to those EPA has questioned in previous section 5 or other government actions. Commercial development would be affected if, as CMA suggests (CMA 1981, p.

III-45 to III-62), potential customers began requiring that a new chemical be cleared through the PMN process before they will test it; and, of course, if the costs of filing the form reduced the expected return below the acceptable level. Also, anecdotal evidence of the effect of the 90-day delay indicates that some chemicals are too time-sensitive to be introduced if subject to a PMN process. The market introduction and response stage could be thwarted if the PMN review resulted in reformulation, if costly workplace controls were required, or if the PMN review resulted in the chemical not being marketed at all.

These potential effects become significant if the costs of the program are large relative to the sums chemical firms spend on innovative activities. In Chapter IV, the total annual costs to industry of the program were estimated to be at most twelve million dollars. ICF recently tried to estimate the total amount spent by chemical companies of new chemical research and development. We found, that existing published data only allows for estimating new product spending. Using a necessarily cumbersome set of separately developed data we inferred total new product spending to be approximately 2.2 billion dollars in 1980. The portion of the new product spending associated with new chemicals could not be determined.

The methodology employed started with NSF data on chemical industry research and development. Then we broke it into three categories (process, new product, existing product) using McGraw-Hill data. Next we used Pharmaceutical Manufacturers Association survey data to remove that portion which could be considered drugs-related. The result was the $2.2 billion estimate (Chem Week 1981, Chem Week 1982, Chem Eng News 1982). Appendix E provides a full documentation of how the estimate was derived.

Because the program costs seem so small relative to the total amount spent by the chemical industry on research and development, it seems intuitively possible that the program has no potential significant innovation effect. However, since the costs of the program per new chemical introduction are between $3,000 and $18,000 dollars, some parties, notably the CSMA, have argued that a significant distributional effect in the form of many fewer new introductions of small volume chemicals is occurring as a direct result of the PMN process (Heiden and Pittaway 1982).

This phenomenon could manifest itself in a reduction in the number of small volume introductions after section 5 took effect. However, the economic value of the lost introductions would not be as great as the percentage decline in introductions because the profits lost from not introducing small volume chemicals are not as great as the profits from an average new chemical introduction. That is, the private return in dollars from small volume chemicals is less than the private return for high volume chemicals so long as the price and profit margin are assumed the same (CMA 1982). Even if prices are higher for small volume products, the prices are generally not high enough to generate profits (in dollars) as great as those earned on high volume products. (For example a $25/kg product with a 50 percent profit rate and 1,000 kg annual production generates a profit of $12,500. A $.50/kg product with a 5 percent profit rate and 1,000,000 kg annual production would generate $25,000 in profits.) Thus, even if there was a substantial reduction in the number of new products, there might be only a small overall economic effect. The rest of this chapter explores some estimates of the change in new product introductions and in overall research and development spending on new product since 1978.

B. THE CSMA STUDY

The Regulatory Research Service (RRS) performed a study for CSMA in 1981 on the impact of TSCA on innovation in the chemical specialties industry.[24] (Heiden and Pittaway 1982.) The purpose of the study was to define the nature of the TSCA impacts and to obtain baseline data that could trace the effects of TSCA on innovation over time. To collect data, a survey was made of the membership of CSMA. The survey data for new introductions for 1976, and 1978 through 1981 are used here. Data for 1977 were not included because no data for that year were obtained by the survey. Data for 1979 were not used because no meaningful allocation could be made between pre- and post-PMN periods (PMN filings began in Mid-1979).

The RRS study was based on a sample drawn from members of CSMA. Attempts were made to obtain data from non-member firms in the chemical specialties industries, but none of the responses proved to be usable. RRS developed two surveys, one for the product manufacturers of the CSMA and one for the ingredient suppliers. The samples for the two surveys overlapped, because five of the ingredient suppliers are also product manufacturers. In our analysis, only survey responses from the ingredient suppliers survey were used, because the product manufacturers are formulators that by definition do not develop new chemical substances.[25] The ingredient suppliers sample was very small (18 firms).

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[24] The chemical specialties industry cannot be precisely defined. Generally, it includes firms that produce chemicals that end up in household use, such as adhesives, detergents, fragrances, gasoline additives. Firms that produce chemical specialties range from the formulators to such giants of the industry as Dow and Dupont (both of whom are members of CSMA).

[25] In the Heiden and Pittaway study, some new chemical substance development is shown for product manufacturers. According to a CSMA spokesman, this is a result of the product manufacturers doubling as ingredient suppliers to themselves.

Although no statistical data were given, the authors of the study concluded that the sample was roughly representative of the entire population of ingredient suppliers, both within CSMA and of the entire chemical specialties industry. (Telephone conversation with Heiden and Pittaway on April 26, 1982 and April 27, 1982.) The authors based this conclusion on their knowledge of the respondents and of the chemical specialties industry.

No assertion--statistical or otherwise--was made to the representativeness of the sample to the chemical industry as a whole. Because of the lack of statistical data, no attempts could be made by RRS to weight the sample to make it representative of either the chemical specialties industry or the entire chemical industry.

RRS defined a new introduction as a new chemical substance developed and made available for customer evaluation, similar to but more inclusive than the section 5 definition of a new substance requiring a PMN. The RRS definition is more inclusive because it includes test market chemicals and, more importantly, because it includes certain chemicals manufactured for R&D purposes, which are totally exempt from the PMN requirements.

The RRS survey, by tracking the same sample of firms in 1976, and then from 1978 through 1981, yields the only set of pre- and post-PMN data based on a single sample of firms both before and after the start of the PMN program. Second, it provides the data on new chemical substance introductions segmented by size of firm for the years prior to 1979.

The RRS study showed average introductions for the sample in 1976 and 1978 to be 168 chemicals per year. In 1980-1981, the average was 123.5. On the basis of this information, ICF concluded that a 23.5 percent (168-123.5/168) reduction in new product introductions occurred between the periods 1976-1978 and 1980-1981. According to RRS, the firms with less than $100 million dollars in annual sales accounted for all of the decline (Heiden and Pittaway 1982, p. 2 of Executive Summary). To the extent that small sales volume companies are correlated with small production volume chemicals, this information would tend to confirm the hypothesis that most of the impact of section 5 falls on small volume chemicals.

Additionally it is possible to combine this information with information from the NERA study (see below) of the effect of TSCA to crudely estimate how much of a reduction in profits the 23.5 percent might represent. In Table 5.11 of the NERA study the average third-year sales volume of a new chemical substance for firms under $100 million in annual sales was $124,800. For the average firm, the sales were $741,000. By weighting the averages by numbers of firms in the samples, the average third-year sales of $918,000 was computed for firms with greater than $100 million in sales. If we assume that average expected profit-margins are the same across firm size, then the economic value of new chemical introductions by firms with less than $100 million in sales is 1/6 that of the average company. Thus a 23.5 percent decline in small company introductions would represent a 4 percent decline in the profits from new chemical substance innovation.

The RRS analysis goes on to make two additional points that tend to suggest that the hypothesized effects on the research and development process are in fact occurring. First, it states that the innovation decline appears to have taken the form of a reduction in the more speculative types of innovation; i.e., those developed for a firm's general market, rather than those presumably less speculative activities initiated in response to customer requests. This could be a manifestation of a turning away from basic research. Second, they note that product manufacturers (as distinct from ingredient manufacturers) have not experienced significant declines in innovation. Thus a shift to new product innovation and away from new chemical innovation could be taking place in the allocation of R&D budgets. (In the chemical specialties markets, new products are often reformulations of existing chemicals. These new products would not be subject to PMN.)

C. THE NERA STUDY

The National Economic Research Associates (NERA) performed a pilot study of TSCA-related impacts for the Chemical Manufacturers Association (CMA) (NERA 1981). The objective of the study was to develop and test a methodology for assessing the impacts of compliance with TSCA. In the course of the study, NERA surveyed the CMA membership to develop information that would allow a preliminary evaluation of the impacts of regulation. As best as can be determined, the CMA membership does not include firms with manufacturing activities outside of SIC codes 28 (chemical manufacturing) or 291 (petroleum refining). Thus, the survey data do not cover chemical innovation outside the chemical or petroleum industries.

NERA obtained usable data from 36 of the 170-odd members of the Chemical Manufacturers Association. The 36-firm sample is small, self-selected, and skewed heavily towards large firms. NERA made attempts to weight the sample to make it representative of the industry as a whole, but the weighting process may have made the sample less, rather than more, representative.

New introductions were defined by NERA as substances introduced into commerce that would not have been on the TSCA inventory, if such an inventory had existed for the pre-inventory period. This definition is essentially equivalent to the TSCA section 5 definition, with one possible exception. The language of the NERA survey might cause companies to report new chemicals undergoing test marketing evaluation by the customers of the firm. The section 5 regulations specifically allow an exemption for test-marketed chemicals from full notification requirements. Because we could not definitely conclude that test-marketed chemicals were in the NERA sample, we did not adjust for it.

The survey respondents were instructed to consider a chemical introduction as new unless there was evidence to the contrary. The first edition of the TSCA inventory was not published until the middle of 1979, so there was no positive way of checking if a substance introduced before 1979 was truly new or just new to the firm. Therefore, given the instructions that a product be considered new unless there is evidence to the contrary, and that no positive way of checking exists, substances that were not new could have been counted as new in the survey results. The NERA data are reduced to eliminate as best as possible chemicals that were not genuinely new using the percentage of PMNs submitted that were subsequently determined to be on the EPA inventory.

Overall, four major problems with the NERA study are:

1) It is based on a small, self-selected sample skewed heavily towards large firms;

2) It does not include introductions from outside SIC codes 28 and 2911, and does not extrapolate to cover these chemical activities;

3) It probably counts test-marketed chemicals as new introductions; and

4) It probably includes some chemicals as new innovations when they were only new to the firm, not society.

NERA attempted to correct the first problem. ICF made adjustments based on PMN data to compensate partially for the other three problems.

A major advantage of the NERA study is that survey respondents are identified by company name. This enabled ICF to track new chemical substance introductions for the identical sample from 1973 through 1981, using NERA data for the period 1973 through 1979, and EPA's PMN file data for 1980 and 1981.

NERA concluded that there were about 1700 new chemicals introduced annually prior to section 5's implementation. Furthermore, they estimated that almost 1000 of these were introduced by firms with less than $100 million in sales. Using confidential data in the EPA files, adjusted to be consistent with the NERA survey data,[26J] ICF estimated the change in new product introductions by the 36 surveyed firms. For these 36 companies, innovation as measured by number of PMNs submitted was up on average 20 percent. However, the rise was due entirely to an increase by large companies with small companies showing declines. (See Chapter VI for a more detailed discussion of the findings of the NERA study with respect to small business effects).

In order to better understand these results, ICF broke the 36 companies into strata based on firm size to see what this result would indicate for the industry overall, using the NERA weighting methodology. ICF found that the NERA weighting methodology gave great weight to small sales volume chemical companies so that changes in new introductions by the surveyed small companies created large swings in the estimates of total industry new chemical products. Using the NERA weighting methodology, a 26 percent overall decline in new introductions was projected. Furthermore, ICF found that the estimate

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[26J] Corrections were made to eliminate intermediates, test marketing chemicals, and chemicals already in existence.

for companies with more than $500 million in sales was higher than expected, but that the estimate for companies with less than $500 million was below expected values. This leads to the conclusion that a 26 percent reduction in new chemical introductions occurred, with companies with less than $500 million in sales incurring all of the decline. This result would be generally consistent with the CSMA findings.

NERA noted that the 90 percent confidence interval for their 1700 chemicals per year estimate was 450-3000. ICF determined that 85 percent of this variation was due to variability with number of small company introductions -- the group which the NERA survey covered least well. Because the confidence interval is so great, it is more valid to conclude that there has been no statistically significant change in the number of new chemicals introduced. ICF believes that no conclusions can be drawn about small company innovation until much better data about small chemical company innovative activities is presented.

D. THE ADL STUDY

In December 1978, ADL provided EPA with an economic analysis of the PMN regulations which concluded that if the PMN submission cost was $5,000 - about 30 percent fewer new chemicals would be introduced. Several weaknesses in the ADL study cast doubt on this conclusion. First, almost no documentation for this conclusion exists. Second, ADL provides no analysis for its conclusion that between 700 and 1300 new chemicals were introduced annually in the 1970's. Third, the 30 percent reduction is based on analysis of only 10 chemicals introduced in the past (and ADL does not provide an explanation for how the analysis was performed). Fourth, after ICF determined what ADL had done, it was obvious that ADL had assumed perfectly elastic demand, i.e., no ability to pass through form-filing costs to consumers of the new chemical. Notwithstanding these weaknesses, it is illuminating to see what the ADL approach would predict given the data now available.

As mentioned above, ADL believed that 700-1300 new chemicals (other than drugs and pesticides) were introduced into commerce annually before section 5 took effect. According to Table III-1 of the ADL report, 30 percent of these were produced in quantities of over 1000 lbs., while 70 percent were produced in quantities under 1000 lbs. This is in stark contrast to analysis of the PMN data base that reveals that between 79 percent and 88 percent of all PMNs are expected to be produced in quantities of 2,200 lbs. or more. One explanation for the difference between PMN submissions and ADL's analysis is that the PMNs are projections while the ADL estimate reflected reality (i.e., often new products do not do as well as expected). Another explanation is that section 5 has affected small chemical innovation -- but these numbers suggest drops of magnitudes greater than even the trade associations estimate.

	ADL Estimate[27] (from Table 1)	PMN Data in 1981[27]
Small volume	700	82 - 144
Large Volume	300	540 - 602

In contrast to the ADL figures shown above, ADL's estimate of the decline due to the PMN program was based on a sample of chemicals of which only 30 percent were produced in quantities of less than 1,000 lbs. annually. However, for the following reasons the sample was used:

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[27] For ADL 1,000 lbs. cut-off, for PMNs 1,000 kilogram (2,200 lbs.) cut-off.

- this sample more closely matches the expected production volumes reported in the PMNs;
- patent data indicate much greater numbers of innovations by large companies; and
- the Snell conclusion(Snell 1975) (developed in only two months without using proper survey research techniques) that small companies produce many more innovations than large has not been corraborated by any other research.

As shown in Exhibit IV-16, the cost of the EPA82 form per new chemical entities, for the PMN programs range from $5,600 to $13,100 dollars in 1981 dollars. This cost must be compared to the estimated net present value of the profit stream in 1981 dollars to determine whether, after imposition of the PMN costs, the product still would generate a positive return. In previous work ICF found the estimated net present value of sales (assuming a 15% nominal discount rate) of the 10 ADL chemicals in 1977 to be as shown below. Using the chemical products producer price index to inflate the sales to 1981, we then multiplied by the average profit rate in the chemical industry (6%), to obtain the net present value of the profit stream associated with each of these chemicals.[28] As Exhibit V-1 shows, only one of these ten could not result in a positive return even after imposition of the $5,600 PMN costs. If the true cost per PMN were $13,100, then atmost two of the chemicals would not be introduced. The one chemical represents approximately 0.4% of the total profits associated with the set of chemicals, the two, 2.0%. Assuming that consumer surplus is proportional to producers surplus (and its proxy--reported profits), then the net loss to society was at most 2.0 percent of the pre-TSCA innovation value.

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[28] The costs should be adjusted for tax effects since they represent pre-tax costs. However, given the imprecise nature of this analysis, we have used the pre-tax value to be conservative. That is, this is an estimate of the greatest impact possible.

EXHIBIT V-1

NET PRESENT VALUE OF PROFITS FOR TEN CHEMICALS
(Dollars)

Chemical	1977 NPV of Sales	1981 NPV of Sales	1981 NPV of Profits
1	$36,650	$55,640	$3,338
2	$145,950	$221,574	$13,294
3	$189,830	$288,191	$17,291
4	$316,990	$481,239	$28,874
5	$325,500	$494,159	$29,650
6	$348,450	$529,000	$31,740
7	$394,540	$598,972	$35,938
8	$745,510	$1,131,799	$67,908
9	$818,430	$1,242,502	$74,550
10	$5,191,370	$7,881,297	$472,878

E. CONCLUSIONS

On the basis of limited evidence, it appears that the effects on research and development hypothesized originally in ICF's 1980 report on the economic impact of the PMN rule, as summarized above, were valid. That is, the major effect of the the rule is selective; some of the smaller volume, lower value chemicals probably can not absorb even the relatively low reporting burden represented by the most recent EPA proposals. (Exemptions should significantly reduce this burden). The overall economic effect is considerably less because the value of the profits foregone and the benefit to consumers not obtained from small volume chemicals is much less per chemical than a large volume or high value product. No data indicate that high value or large volume products have been affected by the program. Thus, if an effect on new chemical innovation has occurred, it is likely that this effect has been so small as to be statistically insignificant in a net social welfare sense. That is, both the CSMA and the ADL approaches yield estimated losses of less than 5 percent of the value of innovation prior to TSCA, and the uncertainty around all of these estimates is much, much greater than 5 percent.

CHAPTER VI

SMALL BUSINESS EFFECTS

A. INTRODUCTION

Generically, the effects of federal regulation on small business are of serious enough concern that a statutory remedy designed to mitigate adverse effects has been put in place. In September of 1980, Congress enacted the Regulatory Flexibility Act (P.L. 96-354), which requires that regulatory agencies consider and be sensitive to the potential burdens that regulations may place on small business. Such burdens may be disproportionate because it may be difficult for small business to meet regulatory requirements which fall uniformly on firms of all sizes. Therefore, burdens which larger firms might easily absorb could pose substantial problems for small firms. In theory, such disproportionate burdens could ultimately affect the ability of some small firms to compete with larger firms.

Throughout the evolution of the section 5 program, much concern has been expressed about the potential effects of the PMN reporting requirements on small firms. Such concern has appeared in both comments to proposed rules as well as in various formal analyses (Ansul Company 1979, CMA 1979, SOCMA 1979, ICF 1980, CMA 1981, and Heiden and Pittaway 1982). Among the concerns mentioned have been the following:

- innovation is of the utmost importance to small firms;
- small firms rely on many low-volume chemicals and therefore are likely to have to submit many section 5 notices;

- low-volume new chemicals are the ones most likely to be adversely affected by section 5 requirements; and
- costs associated with the section 5 program will be difficult for small firms to absorb.

In this chapter, these concerns are explained in detail and four previous analyses relating to such effects are reviewed (Section B). It is important to understand that many of the analytical efforts reviewed in Section B were developed from assumptions about primary economic effects which may no longer be representative of the range of primary economic effects associated with the regulatory options now under consideration. Estimates of primary economic effects imposed on small business by the regulatory options currently under consideration are addressed in Section C. In addition, potential effects of the proposed exemption options on small business are addressed in Section D. A chapter summary is provided in Section E.

B. REVIEW OF PREVIOUS ANALYSES

Over the past four years, four economic studies have discussed TSCA's impact on small business in the chemical industry. One of these was prepared for the Chemical Specialties Manufacturers Association (CSMA) (Heiden and Pittaway 1982) and another for the Chemical Manufacturers Association (CMA) (NERA 1981). The other two studies, prepared for EPA, were performed by Arthur D. Little, Inc. (ADL 1978) and ICF Incorporated (ICF 1980). This section reviews each of these studies.

1. The CSMA Study

In 1981 the Regulatory Research Service (RRS) performed a study for CSMA on the impact of TSCA on innovation in the chemical specialties industry

(Heiden and Pittaway 1982).[29] The RRS study is based on a survey sample drawn from members of CSMA. As stated in Section V.B, the average number of new chemical introductions in 1976 and 1978 were 168 per year. In 1980-81, however, the average was 123.5. According to RRS, firms with less than $100 million in annual sales accounted for 98 percent of the decline. Thus, the analysis found a striking difference between section 5 innovation effects on small companies and section 5 innovation effects on large companies. RRS made no claim as to the cause of the decline but implied that it was due to TSCA section 5.

The CSMA study focused on ingredient suppliers and specialty product manufacturers, two large subgroups of the chemical specialties industry. Exhibit VI-1 presents the number of new substances produced by ingredient suppliers in the RRS survey, as a function of time interval and company size. The data suggest that innovation by ingredient suppliers has decreased for firms below $200 million but has increased for firms above $200 million. RRS, however, classifies "small" firms as having sales less than $100 million. Thus, "small" firms and larger ones under $200 million appear to be similarly affected by section 5, based on the data developed by RRS.

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[29] See Section V.B, p. 126 for a definition of the chemical specialties industry.

EXHIBIT VI-1

NEW SUBSTANCES PRODUCED BY INGREDIENT SUPPLIERS IN THE RRS SURVEY AS A FUNCTION OF FIRM SIZE

Size by Total Chemical Sales	1976	1978	1979	1980	(Estimate) 1981
≤ \$100 million (12 firms)					
Firm speculation	69	72	36	40	39
Customer request	64	71	51	59	62
Total	133	143	87	99	101
\$100 - 200 million (2 firms)					
Firm speculation	15	15	10	8	8
Customer request	0	0	0	0	0
Total	15	15	10	8	8
≥ \$200 million (4 firms)					
Firm speculation	10	10	15	10	16
Customer request	5	5	7	7	8
Total	15	15	22	17	24

Source: Heiden and Pittaway 1982, p. II-8.

The study remarks that section 5 costs faced by small firms are less than those faced by large ones. For example, RRS estimates PMN filing costs of \$5,000 for small firms (under \$100 million in sales), \$8,000 for medium firms (\$100 - 500 million), and \$7,800 for large firms (over \$500 million). But the study also supports the view that TSCA is relatively more burdensome to small firms. RRS suggests that the reason small firms face lower per-chemical costs is that they are not willing to incur any higher costs, since they cannot absorb higher costs through the marketing of a large number of new chemicals or large volumes of existing or new chemicals. That is, the opinion held by

RRS and CSMA is that small firms generally market small volume chemicals, and their expected profits from these chemicals cannot compensate for additional, up-front, section 5 costs.

RRS further suggests that an additional burden could exist because small companies lack expertise in PMN filing. For example, these firms may not employ specialists who know precisely what information should be submitted to fulfill PMN data requirements. Therefore, according to the RRS report, small firms face additional problems due to their lack of expertise in regulatory matters.

The CSMA study states that the following observations of ingredient suppliers support their opinion regarding the willingness of small firms to incur PMN filing costs:

- The average present value of profit targets for new chemicals appears to be directly related to the size class of the firm (Exhibit VI-2).
- Managers of small businesses seem more likely to reject marketing a new substance than managers of large businesses, when both face the same regulatory cost (Exhibit VI-3).

The study includes data collected from interviews with the managers of certain ingredient suppliers. These managers were asked if their decision to market a new chemical would be influenced by "an up-front regulatory cost of $7,000 as a pre-condition for commercialization." Of firms with less than $50 million in annual sales, eight of ten "indicated they would seldom, if ever, engage in such development." In contrast, of firms with annual sales over $500 million, only one of seven replied that the up-front cost would significantly affect the decision to market a new chemical. RRS remarks that interview results for firms in the middle range are unconclusive.

EXHIBIT VI-2

AVERAGE PRESENT VALUE OF PROFIT TARGETS PER INNOVATION FOR INGREDIENT SUPPLIERS IN FOUR SIZE CLASSES (15% DISCOUNT RATE)

(Millions of 1981 Dollars)

Overall Firm Annual Sales Size	Average Present Value
< 10	$0.153
11-100	$0.334
101-200	$0.438
> 200	$0.909

Source: Heiden and Pittaway 1982, p. III-27.

EXHIBIT VI-3

AVERAGE REJECTION RATE PER INGREDIENT INNOVATION ASSOCIATED WITH PMN REQUIREMENT, BY DISCOUNT RATE (12, 15, & 20) AND SIZE CLASS OF REPORTING FIRM

Overall Size Class (Millions of 1981 Dollars in Sales Per Year)	No. of Innovations in Sample	Average Rejection Rate					
		Lower Limit Regulatory Cost ($4K)			Upper Limit Regulatory Cost ($18.4K)		
		12%	15%	20%	12%	15%	20%
< 10	10	.17	.19	.23	.51	.58	.70
11-50	11	.12	.12	.14	.35	.38	.42
51-100	4	.16	.17	.19	.47	.51	.58
101-200	2	.11	.12	.15	.32	.36	.43
201-500	3	.00	.00	.00	.01	.01	.01
> 500	8	.00	.00	.01	.01	.02	.02

Source: Heiden and Pittaway 1982, p. III-26.

The study also investigates the extent to which small ingredient suppliers depend on innovation. RRS concludes that ingredient suppliers rely heavily on their ability to market new substances in order to remain viable. Moreover, RRS suggests that this is especially true for small and medium size companies, which generally derive a large portion of their earnings from the sale of substances not in existence five years ago (Exhibit VI-4). Because of this and the greater problems of small businesses to incur regulatory costs, RRS predicts a gradual shift in the market share of chemical ingredients to large companies. Hence, RRS believes there will be less competition in the ingredient industry by small firms as a result of section 5 costs.

EXHIBIT VI-4

ESTIMATED AVERAGE PERCENTAGE OF INGREDIENT SALES ACCOUNTED FOR BY PRODUCTS NOT IN EXISTENCE FIVE YEARS AGO, BY OVERALL FIRM SALES SIZE

Firm Size Class (Millions of 1981 Dollars)	% Sales from Substances Not in Existence Five Years Ago
< 50	16.5%
51 - 200	18.0%
> $200	6.0%

Source: Heiden and Pittaway 1982, p. III-38.

The survey conducted by RRS included 100 firms. Yet data on new substances produced in 1976 and 1978-81 were obtained from only 18 ingredient suppliers. However, 12 of the 18 companies had annual sales of less than $100 million.

The authors of the study conclude that the sample is roughly representative of the entire chemical specialties industry. Although they do not provide statistical data to support this, they base their conclusion on their knowledge of the respondents and of the chemical specialties industry. (From telephone conversations with Heiden and Pittaway on April 26, 1982 and April 27, 1982.) As mentioned in Section V.B, no assertion -- statistical or otherwise -- is made as to the representativeness of the sample to the chemical industry as a whole.

The study generally describes a "small" firm as one having sales less than $100 million. This seems generally consistent with other analyses, although there may be a need to focus on even smaller firms as well. For example, it may be desirable to consider as "small" those firms with annual sales below $30 million.[30]

2. The NERA Study

In January 1981, the National Economic Research Associates (NERA) prepared for CMA a pilot study of the impact of TSCA on the chemical industry (NERA 1981). This study has already been discussed from the standpoint of innovation in Section V.C. For this study, NERA conducted a survey of the industry, and used it to examine the direct and indirect costs to chemical firms of complying with TSCA regulations. The study addresses, as a major issue, the relative impact of TSCA on small chemical companies. In September of the same year, CMA wrote a report that contains the NERA (1981) study and supplements it with CMA's own comments and observations.

CMA believes that TSCA costs are more burdensome to small than to large firms because they decrease the profitability of small firms' new chemical products more than those of large firms. Referring to the survey data, CMA argues that the profitability of small firms is impaired more by TSCA because small firms incur the highest ratio of TSCA-related costs to revenue. That is, compliance costs behave like fixed costs which burden small firms proportionately more than large firms. Exhibit VI-5 presents the TSCA costs per million dollars of domestic sales, by company size, as reported in the CMA study.

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[30] This was one parameter selected by EPA to define small businesses for the purposes of the TSCA Section 8(a) Preliminary Assessment Information Rule (47 FR 26992).

EXHIBIT VI-5

TSCA COSTS PER MILLION DOLLARS OF DOMESTIC SALES,
BY COMPANY SIZE, AS INDICATED BY CMA
(Millions of 1979 Dollars)

Company Size	TSCA Cost Per Million Dollars of Sales
Under 25	$1,311.04
25 - 100	$1,175.87
100 - 200	$346.38
200 - 500	$321.39
500 - 1,500	$429.92
Over 1,500	$542.41

Source: NERA 1981.

The survey data indicate that large firms have higher TSCA regulatory costs, in proportion to their sales, than medium-size firms. Of course, the bulk of this difference may be reflected in non-PMN factors (like Inventory reporting). Another explanation for this is that medium-size firms may introduce the least number of new chemicals in proportion to their revenue. Additionally, there could be two other explanations, assuming NERA's survey data are reflective of the industry: (1) Medium-size firms may produce more new chemicals for which health and safety are generally less subject to question than the new chemicals produced at large firms, and so they incur lower filing costs; (2) Large firms may be willing to spend proportionally more on regulatory measures in order to further ensure against any risks of delay or cancellation, especially when these risks concern high volume substances. Thus, they may be willing to provide very complete data packages to eliminate any "snags" in the PMN review process.

The NERA (1981) study classifies "small businesses" as businesses with less than $100 million in annual sales revenue. It states that small chemical companies "produce a relatively large share of all new chemical substances." In addition, the study remarks that several small businesses are "single-product entities." CMA further believes that many small firms are under continuous pressure to innovate in order to maintain the size of their markets. The report implies that small firms face the most risk, in terms of firm failure, if their innovative capabilities are hindered. Thus, CMA suggests that the impact is two-fold: TSCA imposes on small businesses not only a disproportionate cost burden, but a disproportionate risk and uncertainty burden as well.

CMA maintains that the extra burden which section 5 of TSCA imposes on small companies will lead to an increase in the number of small business failures. The report suggests two main reasons why this would be bad for the country as a whole:

(1) Small business introduce a relatively large proportion of all new chemical substances. Therefore, fewer small companies could result in less innovation;

(2) A reduction in the number of small companies implies higher concentrations in chemical industries, hence, less competition.

The NERA (1981) survey was based on responses of 36 CMA member companies which represented about 20 percent of CMA membership or 23 percent of CMA membership sales. Of the total "chemical industry" as defined by CMA (see below), these firms comprised 14.7 percent in sales.

However, the sample of chemical firms used in the survey is not representative of the entire chemical industry for several reasons. The 36-firm sample is small, self-selected, and skewed heavily towards large firms. For example, only five firms are in the "under $25 million" stratum, though they are used in the study to represent 2,480 of the 3,018 total companies with more than 20 employees in SIC codes 28XX and 2911 (the chemical industry).

To account for an underrepresentation of small firms in the survey sample, NERA (1981) used a "separate ratio method." The survey sample was first divided into six strata based on company size. The two lowest categories were "under $25 million" and "$25-100 million." For any variable under consideration, this method would weight the mean of each stratum by the fraction of sales which that stratum represented in the entire chemical industry. However, firms adversely affected by TSCA regulations may have had more incentive to participate in the study than firms not adversely affected (in order that their burden be reported and analyzed). Therefore, if the survey responses are in fact biased (in any direction), this weighting process potentially exacerbates the distortion in the data.

3. ICF Study

ICF (1980) performed an analysis of the economic impacts of section 5 notice requirements under TSCA (ICF 1980). Part I analyzes the impact on the chemical industry, and one of the issues considered is the variable impact of section 5 on chemical firms of different sizes. To examine the issue, ICF (1980) conducted a meeting of experts on the chemical industry and innovation. Two of the experts were scholars from the academic community who had studied chemical innovation. Three others were independent consultants to the chemical industry who collectively held a total of 100 years of industry experience. The ICF (1980) study presents the opinions of these experts with regard to the impact of TSCA on small chemical companies.

The ICF (1980) study breaks up the chemical industry into four size categories: $0 to $3 million in annual sales, $3 to $10 million, $10 to $200 million, and greater than $200 million. It analyzes the characteristics of different size firms and relates their behavior to possible impacts of section 5 regulation. According to the study, the important distinctions between different size firms are their expected sales volumes for new chemical products and the access they have to expertise on TSCA regulation. ICF states that the expert panel characterized mid-size firms ($10 to $200 million) as having limited information on about regulatory and legal matters. In addition, ICF (1980) said:

> Without expertise in regulatory matters, they would likely choose to take actions that minimized their exposure to the threats posed by regulation. Thus, they should be expected to (1) steer their new product development away from suspect chemicals, and (2) minimize their regulatory and legal costs by simply not marketing any chemical on which EPA makes a request for additional data.

That (ICF 1980) study pointed out that small companies, below $10 million, also have low expected profits on new chemical introductions and a lack of regulatory expertise -- even less than medium size firms. The study remarks that their small managerial staff and legal capability act to increase direct out-of-pocket costs and uncertainty costs. Delays in new chemical introduction are also mentioned as a factor that could burden small businesses more than large ones; the study indicates that small firms have less expertise in trying to avoid delays than large firms.

The report (ICF 1980) adds that small companies and some mid-size companies may not have the legal expertise to protect confidential information submitted to EPA. Therefore, ICF (1980) believes that information requirements under section 5 could provide large companies with an inexpensive way to track their small rivals' new product development.

ICF (1980) predicts that, over the long term, the chemical industry may become more concentrated, and innovative companies may be necessarily larger in order to absorb higher regulatory costs. Furthermore, firms may shift their market strategy toward the consolidation of product lines into high volume products.

The ICF (1980) study does not define "small business" in a manner consistent with that of other studies. For example, what may be true for firms below $10 million, or small companies as discussed in the ICF study, may not be true for firms below $100 million as discussed in the CSMA study. By examining a sample of approximately 500 PMNs submitted in 1980-81, ICF found that the number of companies submitting PMNs with annual sales less than $30 million is about twice that of companies with sales less than $10 million. Hence, the $10 million definition of small is limited in its applicability.

4. ADL Study

ADL released its study in December 1978 (ADL 1978), so much of its content does not reflect the current reality of the section 5 program.

Nevertheless, the study's general comments on the impact of TSCA on small companies are still relevant. These comments are:

- The per chemical filing costs incurred by small firms tend to be lower then those of large firms. ADL believes this is because small firms do not have as much access to information as large firms, and therefore, they would supply less, incurring lower per-chemical costs.
- Regardless of their lower per-chemical filing costs, small firms are potentially burdened more by section 5 because filing costs represent a higher proportion of the profit stream from small-volume chemicals.
- Small companies are less willing to cope with the potential uncertainties and risks associated with the section 5 program and therefore would likely redirect themselves away from new chemical innovation.

The data to support these conclusions were developed under tight time deadlines and therefore may not be as complete as they otherwise might have been. Also, it is important to note that the nature of the section 5 Program, as analyzed by ADL (1978), differs significantly from the regulatory options now under consideration.

5. Summary of Previous Studies

Clearly, the consensus from previous analyses is that the section 5 program potentially results in disproportionate economic effects on small businesses. These findings have contributed towards the evolution of the section 5 program to the current set of regulatory alternatives. The effects of these alternatives on small businesses are discussed in Section C. Furthermore, the proposed exemptions policy further mitigates the potential economic effects on small businesses. These are discussed in Section D.

C. ESTIMATED COST TO SMALL BUSINESS AND IMPACT ANALYSIS

Most of the studies discussed previously draw the conclusion that the potential exists for small business to be adversely affected by the section 5 premanufacture notification requirements. In this section, the magnitude of the potential impact is determined after developing a definition of a small business for TSCA section 5 analysis purposes. Using the PMN data base and the costs developed in Chapter IV, the amount of cost imposed on small business is computed. Because these costs are based only on actual PMN submissions by small companies, they potentially understate total costs on small business. This is true because previous studies discussed in Section VI.B suggest that there may also be costs associated with not commercializing chemicals which become unprofitable as a result of section 5 requirements. However, the magnitude of these costs are not known with sufficient certainty to include them in the analysis. Also in this section, the program cost to small business (as estimated from PMN submissions) is compared to two measures of the financial health of small business -- sales and profitability; and the section 5 cost per new chemical is compared to expected new chemical sales and profits.

1. Definition of Small Business

Several sources exist for the definition of small business, including the Small Business Administration, industry, and EPA. The Small Business Administration (SBA) defines small businesses by SIC codes. For each 4-digit code, the SBA develops employment cut-offs that firms cannot exceed if they are to qualify as a small businesses for purposes of government procurements and often for special treatment under certain government programs. For the chemical industry and certain other industrial sectors most affected by the PMN requirements, the cut-off has generally been either 1,000 or 500 employees per firm. Based on data from the latest Census of Manufactures, sales per employee in the chemical industry (Major Group 28) are $134,000 in 1977 dollars (USDOC, 1981). When inflated to December 1981 dollars using the Producer Price Index for Chemicals and Allied Products, this estimate becomes $203,000 per employee. Thus, the SBA definitions of 500 or 1000 employees translate to cutoff points of approximately $100 million or $200 million in annual sales.

The chemical industry has defined small entities for certain surveys it has conducted. In 1975, Foster D. Snell chose a definition of $30 million of sales in 1972. This amount would be $84 million today, based on the change in the Producer Price Index for Chemicals and Allied Products from 1972 to December 1981. NERA's study used a $100 million sales level in 1979. RRS's study for the Chemical Specialties Manufacturers' Association used $30 million in 1981 sales.

The final alternative to consider concerns the TSCA definitions used in section 8. EPA has tailored the definition to the particular purpose that the regulation serves. For Inventory reporting in 1978, a situation in which a comprehensive list of all chemicals manufactured was sought, the small business definition chosen was $5 million in sales in the most recently completed fiscal year. For the 8(a) Level A rule, a $30 million cut-off was chosen.[31] ICF noted (in ICF 1980) that its panel of industry experts considered $20-$30 million in annual sales to be the point at which the research and development processes of a company changed from being primarily entrepreneurial to being slightly formalized.[32]

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[31] Both these definitions included other considerations such as production volume of specific chemicals.

In conclusion, either the $30 million or $100 million sales levels may be appropriate cutoffs for defining small chemical firms for innovation analysis purposes. Therefore, for completeness, this analysis is performed for both definitions.

2. Estimate of Impact on Small Business

ICF analyzed a sample of approximately 500 PMNs submitted in 1980 and 1981 to assess the extent to which small business incurred the cost of the program. Approximately 6.7 percent of the PMNs were submitted by 14 companies with sales of less than $30 million during the year in which the PMN was submitted. Furthermore, approximately 12.6 percent of the PMNs were submitted by 29 companies with sales of less than $100 million. Thus, small companies on average can be expected to absorb these percentages of the total industry costs of the program. From Exhibit IV-15, the total industry program costs are $4,838,000 to $11,432,000 annually, given use of the EPA82 form. Assuming per-PMN costs are constant across all firm sizes, firms with less than $30 million in annual sales then must absorb costs in the range of $324,000 to $766,000 (6.7% of the total cost). Firms with less than $100 million in annual sales must absorb $610,000 to $1,440,000 (12.6% of the total industry costs).

The effect of these costs on these firms is measured by comparing the section 5 costs to the total sales volume and estimated annual profits of the smaller companies. The 14 companies in the sample with less than $30 million in sales averaged $12 million in sales. This estimate of average annual sales was derived from EPA data developed from several sources. It is interesting to note that this estimate of $12 million in average annual sales for 14 companies with less than $30 million in annual sales is somewhat higher than the estimate developed in economic analysis conducted to support TSCA section 8(a) rulemaking. According to the Office of Pesticides and Toxic Substances, EPA (OPTS 1981), 312 companies with less than $30 million in sales averaged $6.5 million in annual sales.

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[32] The experts also noted that around $200 million in sales the process almost certainly becomes totally formalized.

Assuming EPA receives a total of 900 PMN submissions per year, the total sales of small companies submitting PMNs each year would be $317 million. This estimate was derived by multiplying the total sales for these 14 companies by the ratio of 900 PMNs to the number of PMNs in the sample. Thus the cost ($324,000 to $766,000) is only .1 percent to .24 percent of total sales. Assuming industry pre-tax profit margins of 12 percent,[33] the cost would represent 0.9 percent to 2.0 percent of profits. These ratios were calculated assuming pre-tax costs and pre-tax profits. The same ratios would hold if costs and profits were both specified on an after-tax basis.

When considered in the context of the larger definition for small firms (annual sales less than $100 million), the impacts are even less. The adjusted total annual sales of these companies is approximately $2 billion. The $610,000 to $1,440,000 total cost is between .03 percent and .07 percent of sales, and is 0.3 percent to 0.6 percent of profits of these firms, assuming a pre-tax profit margin on sales of 12 percent.

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[33] For industrial chemicals and synthetics, after-tax return on sales averaged 5.9% for the first three quarters of 1981 (CEA 1982, p. 332). Assuming a corporate income tax rate of 50%, pre-tax profit margins are assumed to be double after-tax margins.

Exhibit VI-6 summarizes these findings.

EXHIBIT VI-6

IMPACT OF TOTAL PMN COST TO SMALL BUSINESS MEASURED AS A PERCENTAGE OF SALES AND PROFITS

Small Business Definition	Sales	Profits
Annual Sales < $30 million*	.10 - .25%	0.9 - 2.0%
Annual Sales < $100 million**	.03 - .07%	0.3 - 0.6%

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*Average sales of firms in this category are about $12 million annually.
**Average sales of firms in this category are about $36.6 million annually.

3. Estimate of Impact on Typical New Chemical Introduced by Small Business

Using data on PMN submissions, ICF examined the ability of small firms to absorb PMN filing costs. A sample of approximately 500 PMNs, all of which were submitted in 1980-81, were analyzed. For this sample, there were 14 companies with annual sales less than $30 million which submitted PMNs. ICF calculated the average expected production volume per new chemical for each of these companies. The average expected production volume per new chemical per "small company" was then derived by averaging expected production volume across all firms with sales less than $30 million. This average was 103,848 kilograms expected volume, per new chemical, per small company annually.

ICF used this expected annual volume figure in the following sensitivity analysis of the profits of small companies. The range of prices for the new chemical was assumed to be between .50 and 2.00 dollars per kilogram. When applied to the annual production volume of 103,848 Kg., this price range translates into a range of annual sales for the new chemical of $52,000 -

$208,000. Assuming alternative pre-tax profit margins on sales of 12 percent, 30 percent, and 60 percent (which correspond to after-tax margins of 6 percent, 15 percent, and 30 percent[34J]), ICF derived ranges of possible annual profits associated with these profit margins. Then, assuming a constant profit yield for ten years and a real discount rate of ten percent as specified by the Office of Management and Budget (OMB, 1981), the present value of profits that would result from the sale of a new chemical by a small firm was estimated. This present value was estimated for each of the three possible profit margins, as shown in Exhibit VI-7. ICF then performed exactly the same analysis for firms with annual sales less than $100 million. Exhibit VI-8 summarizes this second analysis.

EXHIBIT VI-7

DERIVATION OF PRESENT VALUE OF PROFITS FOR EACH OF THE ALTERNATIVE PROFIT MARGINS, FOR A NEW CHEMICAL BY A FIRM WITH ANNUAL SALES LESS THAN $30 MILLION

Price Range: $.50 - 2.00/Kg
Annual Production Volume: 103,848 Kg.
Revenue Range: $52,000 - 208,000

Profit Margin	Annual Profit Range	10-Year PV of Profit Range (10% Discount)
12%	$6,200 - $25,000	$38,000 - $154,000
30%	$15,600 - $62,400	$96,000 - $383,000
60%	$31,200 - $124,800	$192,000 - $767,000

[34J] Six percent derived from industry average ROS (CEA, 1982). Thirty percent roughly derived from NERA (1981) average third year profits from less than $500,000 new chemical sales markets divided by average third year sales from those markets (actual value 35.4%). Fifteen percent derived from NERA (1981) average third year profits from all new chemical markets divided by average market size (actual value 16.7%).

EXHIBIT VI-8

DERIVATION OF PRESENT VALUE OF PROFITS FOR EACH OF THE ALTERNATIVE PROFITS MARGINS, FOR A NEW CHEMICAL BY A FIRM WITH ANNUAL SALES LESS THAN $100 MILLION

Price Range: $.50 - 2.00/Kg
Annual Production Volume: 389,036 Kg.
Revenue Range: $195,000 - 778,000

Profit Margin	Annual Profit Range	10-Year PV of Profit Range (10% Discount)
12%	$23,400 - $93,400	$144,000 - $574,000
30%	$58,500 - $233,400	$359,000 - $1,434,000
60%	$117,000 - $466,800	$719,000 - $2,868,000

Taking the total EPA82 Form cost estimate from Exhibit IV-15 and dividing by 900 PMNs per year yields the estimated cost of submitting a PMN as $5,400 - $12,700. ICF compared this cost estimate with the present value of per-chemical profits for three cases. The "best" case for both types of small firms is the lowest possible PMN cost ($5,400) along with the highest possible present value of profits ($767,000 for firms below $30 million). Similarly, the worst case is the highest possible PMN cost and the lowest possible present value for per-chemical profits. Finally, the average case combines the mid-range of both the PMN cost per-chemical ($9,050) and the present value of profits per chemical for a 30 percent pre-tax profit margin.

Exhibit VI-9 illustrates the best, average, and worst cases that might occur from the possibilities considered in this analysis.

EXHIBIT VI-9

PMN COST AS A PERCENT OF PRESENT VALUE OF EXPECTED PROFITS

Type of Firm	Best Case	Average Case	Worst Case
Sales Below $30 Million	0.7%	4%	33%
Sales Below $100 Million	0.2%	1%	9%

In conclusion, in a worst-case situation, firms below $30 million in sales could sometimes incur a section 5 cost which could approach 33 percent of the present value of their expected profits. For firms with sales less than $100 million, this worst-case estimate is about 9 percent. Therefore, ICF concludes that in a worst-case situation, small firms (especially those below $30 million in annual sales), could potentially be significantly affected by section 5. The respective percentages for the average-case situation are approximately 4 percent for firms below $30 million and 1 percent for those below $100 million. In the best situation, all small firms incur costs which are less than 1 percent of the present value of the profit stream. It is also important to understand that all of the above estimates do not incorporate any savings due to the proposed exemption rules. These exemptions will reduce the burden on small firms, as discussed below in Section D.

D. EFFECTS OF PROPOSED EXEMPTION RULES ON SMALL BUSINESS

This subsection discusses the effects of the proposed exemption rules on small business. It uses a methodology consistent with that presented in Section F of Chapter IV. That is, it utilizes a sample of approximately 500 PMNs considered representative of all PMNs submitted to date to estimate the number of PMNs submitted annually by small business, the proportion of those PMNs which would be subject to exemptions under the proposed rules, and the approximate savings to small business which are attributable to the proposed exemptions. These estimates are based on the assumption that the exemption rules will not affect the rate of section 5 submissions from small business. Because the exemptions could conceivably reduce the perceived barriers to new chemical development, it may well be true that the rate of new chemical development would be higher under the exemption rules than in their absence. Therefore, the estimates presented here are probably more representative of lower bounds on the savings to small business due to the proposed exemptions rules.

In order to put the small business savings into perspective, it will be useful to briefly summarize the findings presented in Section F of Chapter 4. The major findings were as follows:

- Based on a sample of approximately 500 PMNs, 64 percent of all PMNs would be eligible for some type of exemption.
- Total savings to submitters would be between $1.0 and $3.7 million, based on an assumed submission rate of 900 PMNs per year. This represents between 20 and 33 percent of total industry costs associated with the EPA82 form.

With respect to small firms, analysis of the sample of approximately 500 PMNs yielded the following information:

- Firms with annual sales less than $30 million submitted 6.7 percent of all PMNs. However, 62.5 percent of the submissions from these firms would be eligible for some type of exemption.
- Firms with annual sales less than $100 million (including the above firms) submitted 12.6 percent of all PMNs. However, 50 percent of the submissions from these firms would be eligible for some type of exemption.

Statistically, one would accept the hypothesis that PMN submissions from firms under $30 million in annual sales qualify for exemption at the same rate as PMNs in general (62.5 percent for firms with sales under $30 million versus 64 percent overall). However, for firms with sales under $100 million, such a hypothesis cannot be accepted. A chi square test applied to samples of exempted PMNs from firms with sales less than $100 million and a sample from firms with sales greater than $100 million showed them to be statistically different. This phenomenon is best explained by the fact that for the data analyzed, firms with sales between $30 million and $100 million do not seem to benefit from the low-volume exemption for very small chemicals (less than 1000 kg.) whereas very small firms and large firms both seem to benefit. At the present time, it is not known whether this is an artifact of the sample, or an accurate reflection of innovation behavior by firms of these sizes. Exhibit VI-10 provides estimates of the important exemption parameters for three non-mutually exclusive size classes, including the distribution of potential exemptions by exemption type.

EXHIBIT VI-10

ESTIMATES OF EXEMPTION PARAMETERS BY SIZE CLASS

	Firms < $30 million in Sales	Firms < $100 Million in Sales	All Firms
Proportion of PMNs	7%	13%	100%
Proportion of PMNs submitted which are eligible for exemption	63%	50%	64%
Exemption Type			
Photographic	0%	0%	5%
Zero-Day Polymer	20%	16%	20%
14-Day Polymer	5%	10%	24%
Low Volume (< 1,000 Kg.)	35%	24%	24%
Low Volume (< 10,000 Kg.)	40%	50%	25%
Site Limited	0%	0%	6%
Total	100%	100%	100%

Source: Sample of approximately 500 PMNs.

Based on these data, it is possible to construct the following estimates for each size class, assuming a total annual submission rate of 900 chemicals:

- number of PMNs submitted,
- number of PMNs eligible for exemptions, and
- number of PMNs eligible for exemptions in each exemption category.

Ehibit VI-11 contains these data.

EXHIBIT VI-11

ESTIMATES OF PMN SUBMISSIONS AND POTENTIAL EXEMPTIONS BY SIZE CLASS

	Firms < $30 million in Sales	Firms < $100 Million in Sales	All Firms
Number of PMNs Submitted	60	113	900
Number Eligible for Exemption	38	57	576
Exemption Type			
Photographic	0	0	29
Zero-Day Polymer	8	9	115
14-Day Polymer	2	6	113
Low Volume (< 1,000 Kg.)	13	14	138
Low Volume (< 10,000 Kg.)	15	28	144
Site Limited	0	0	35
Total	38	57	576

As can be seen in Exhibit VI-11, 38 of 60 submissions (63%) from firms under $30 million in annual sales are eligible for some type of exemption, while 57 of 113 submissions (50%) from firms under $100 million in annual sales are so eligible.

Exhibit VI-12 displays the savings due to the proposed exemption policy for firms with less than $30 million in annual sales. Form filing savings were based on the difference between form filing costs for the EPA82 form and the form filing costs for the various exemption notices as estimated in Exhibit IV-11 (pg. 110). Costs of delay were based on the estimated present value of the per-chemical profit stream for firms under $30 million in sales, as estimated in Exhibit VI-7. The total estimated savings to these firms due to the proposed exemptions rules are $33,000 - $317,000. When delay costs are calculated based on the range of profit streams used in Exhibit VI-12, total costs for the 60 PMNs expected to be submitted by these firms are estimated as $310,800 - $900,000 (assuming all costs associated with the EPA82 form). The proposed exemptions would therefore result in a savings of 11 percent to 35 percent of total PMN costs for this class of companies. This is consistent with the savings generally attributable to the exemptions policy for all firms.

Exhibit VI-13 displays the savings due to the proposed exemption policy for firms with less than the $100 million in annual sales. Form filing savings were estimated as described above. Delay savings were based on the best available data regarding the present value of the per chemical profit streams for companies of this size. This data suggested a range of $144,000 to $2,868,000 as shown in Exhibit VI-8. Total estimated savings to these firms due to the proposed exemptions policy are $71,000 to $973,000. When delay costs are calculated based on the range of profit streams used in Exhibit VI-13, total costs for the 113 PMNs expected to be submitted by these firms are estimated as $646,360 - $2,913,140. Thus, the savings due to the

EXHIBIT VI-12

EXEMPTION SAVINGS FOR FIRMS WITH LESS THAN $30 MILLION ANNUAL SALES
(1981 Dollars)

# of PMNs	Category	Form Filing Cost Without Exemption	Form Filing Cost With Exemption	Savings
Form-Filing Savings[1]				
8	Zero-Day Polymer	9,600 - 49,600	1,680 - 2,960	7,920 - 46,640
2	14-Day Polymer	2,400 - 12,600	340 - 960	2,060 - 11,440
13	Low Volume (< 1,000 Kg.)	15,600 - 80,600	2,210 - 6,240	13,390 - 74,360
15	Low Volume (< 10,000 Kg.)	18,000 - 93,000	14,400 - 33,900	3,600 - 59,100
				$26,970 - $191,540
Delay Savings[2]				
8	Zero-Day Polymer	1,600 - 31,520	110 - 2,160	1,490 - 29,360
2	14-Day Polymer	400 - 7,880	70 - 1,490	330 - 6,390
13	Low Volume (< 1,000 Kg.)	2,600 - 51,220	480 - 9,680	2,120 - 41,540
15	Low Volume (< 10,000 Kg.)	3,000 - 59,100	560 - 11,170	2,670 - 54,070
				$6,380 - $125,220
Total Savings				$33,350 - $316,760
Total Savings (Rounded)				$33,000 - $317,000

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[1] Per-chemical form-filing costs without exemption are assumed to be $1,200-$6,200, as determined by dividing total form-filing costs in Exhibit IV-16 by 900 chemicals. Per-chemical form-filing costs with exemptions are provided in Exhibit IV-11.

[2] Delay costs use the methodology developed in Chapter IV.B.3 (p. 83). However, direct costs of delay are based on an estimated pre-tax profit stream of $38,000-767,000 per chemical for firms with under $30 million in annual sales and a 10 percent real rate of return as mandated by OMB. Therefore per-chemical delays without exemptions are estimated to be: Profits x 3.2% (value of delaying 4 months at 10% real rate of return) x .8825 (% of PMNs not withdrawn nor intermediates associated with other PMNs) x .46 (% of remaining PMNs for which EPA receives a commencement of manufacture notice) x .395 (% of remaining PMNs for which EPA receives a commencement notice within 30 days of expiration of review period) = $200 - 3,940. Per chemical delays with exemptions are calculated similarly, only with different delay periods, as explained in Section IV.B.3.

EXHIBIT VI-13

EXEMPTION SAVINGS FOR FIRMS WITH LESS THAN $100 MILLION ANNUAL SALES

(1981 Dollars)

# of PMNs	Category	Form Filing Cost Without Exemption	Form Filing Cost With Exemption	Savings
Form-Filing Savings[1]				
9	Zero-Day Polymer	10,800 - 55,800	1,890 - 3,330	8,910 - 52,470
6	14-Day Polymer	7,200 - 37,200	1,020 - 2,880	6,180 - 34,320
14	Low Volume (< 1,000 Kg.)	16,800 - 86,800	2,380 - 6,720	14,420 - 80,080
28	Low Volume (< 10,000 Kg.)	33,600 - 173,600	26,880 - 63,280	6,720 - 110,320
				$36,230 - 277,190
Delay Savings[2]				
9	Zero-Day Polymer	6,660 - 132,480	460 - 8,110	6,200 - 123,370
6	14-Day Polymer	4,440 - 88,320	840 - 16,710	3,600 - 71,610
14	Low Volume (< 1,000 Kg.)	10,360 - 206,080	1,960 - 38,980	8,400 - 167,100
28	Low Volume (< 10,000 Kg.)	20,720 - 412,160	3,920 - 77,960	16,800 - 334,200
				$35,000 - 696,280
Total Savings				$71,230 - $973,470
Total Savings (Rounded)				$71,000 - $973,470

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[1] Per-chemical form-filing costs without exemption are assumed to be $1,200-$6,200, as determined by dividing total form-filing costs in Exhibit IV-16 by 900 chemicals. Per-chemical form-filing costs with exemptions are provided in Exhibit IV-11.

[2] Delay costs use the methodology developed in Chapter IV.B.3 (p. 83). However, direct costs of delay are based on an estimated pre-tax profit stream of $38,000-767,000 per chemical for firms with under $30 million in annual sales and a 10 percent real rate of return as mandated by OMB. Therefore per-chemical delays without exemptions are estimated to be: Profits x 3.2% (value of delaying 4 months at 10% real rate of return) x .8825 (% of PMNs not withdrawn nor intermediates associated with other PMNs) x .46 (% of remaining PMNs for which EPA receives a commencement of manufacture notice) x .395 (% of remaining PMNs for which EPA receives a commencement notice within 30 days of expiration of review period) = $200 - 3,940. Per chemical delays with exemptions are calculated similarly, only with different delay periods, as explained in Section IV.B.3.

proposed exemptions rules are 11% - 33% of total PMN costs expected to be incurred by firms with annual sales under $100 million. This is consistent with the finding for firms under $30 million in sales, as well as all firms in total.

In conclusion, the proposed exemption rules will significantly reduce the burden on small firms. For firms under $100 million in annual sales, saving would appear to be between 11% - 33%. Similar saving are projected for firms under $30 million in annual sales. Because projected savings for all firms are between 20% and 30%, it would seem that the smallest firms (those under $30 million) benefit from the proposed exemption rule at roughly the same rate as large firms. However, firms between $30 and $100 million in sales do not appear to gain as much. There is no evidence that large firms will overly benefit from the proposed exemption rules, at the expense of small firms.

E. SUMMARY OF SMALL BUSINESS EFFECTS

In this chapter, four previous analyses were discussed which noted the potential for disproportionate effects on small business resulting from the section 5 program. These findings have contributed towards the evolution of the section 5 program to the current set of regulatory alternatives.

Direct costs to small manufacturers were estimated using the sample of approximately 500 PMNs discussed in Chapter II. Firms with less than $30 million in annual sales were found to submit 6.7 percent of the PMNs while firms with less than $100 million in annual sales were found to submit 12.6 percent of the PMNs. Exhibit VI-14 provides estimates of total costs, and the percentage of sales and profits represented by these costs:

EXHIBIT VI-14

COSTS OF SECTION 5 PROGRAM TO SMALL BUSINESS
(1981 Dollars)

Small Business Definition	Total Cost	Cost/Sales	Cost/Profits
Annual Sales < $30 million*	$324,000- $766,000	0.10-0.24%	0.9-2.0%
Annual Sales < $100 million**	$610,000-$1,440,000	0.03-0.07%	0.3-0.6%

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*Average sales of firms in this category are about $12 million annually.
**Average sales of firms in this category are about $36.6 million annually.

However, because this analysis is based on chemicals which, by definition, were those submitted by small firms which could absorb the PMN costs and remain profitable, the cost estimates could be biased downward. The PMN data base provides no informmation on chemicals which might have been commercialized in the absence of the section 5 program.

Yet to the extent this phenomenon exists, it will be mitigated somewhat by the proposed exemption rules. Because the exemptions could conceivably reduce the perceived barriers to new chemical development, it may well be true that the rate of new chemical development would be higher under the exemption rules than in their absence. For firms under $30 million in annual sales, the proposed exemptions would result in a savings of 11 to 35 percent of total PMN costs. For firms under $100 million in annual sales, the expected savings are 11 to 33 percent of total PMN costs. These estimates could be more representative of lower bounds on the exemption-related savings to small business because it reduces the perceived barriers to new chemical development. In general, there is no evidence that large firms will overly benefits from the proposed exemption rules at the expense of firms with under $30 million in annual sales.

CHAPTER VII

HEALTH IMPLICATIONS OF REGULATORY ACTIONS RESULTING FROM ALTERNATIVE PMN REPORTING FORMS

A. INTRODUCTION

The following chapter discusses and projects human health impacts that might have been associated with regulatory decisions taken by EPA due to differences in the types and amounts of information supplied by the three alternative PMN forms. This analysis of human health impacts is based on a study of PMN cases performed by the Industrial Chemistry Branch (ICB), Economics and Technology Division, of OTS (Farris, 1982). The objective of the ICB study was to review PMNs for which the Agency had taken regulatory actions and to determine whether use of any one of the three alternative forms would not have resulted in identification of the respective PMN chemicals for Agency action. The health impacts which are discussed in this chapter constitute only the differential effects associated with the use of the alternative PMN reporting forms for the particular cases examined. They do not in any way constitute a summary of the health benefits of the entire PMN program.

B. OVERVIEW OF THE ICB PMN STUDY

The intent of the Industrial Chemistry Branch study was four-fold. It was intended to:

- identify the PMN form data elements critical for comprehensive, accurate, and informed PMN reviews;

- identify the source(s) of data for critical elements;
- determine whether use of any of the three alternative PMN forms would have resulted in the Agency's failure to identify risk factors due to lack of data; and
- evaluate the extent to which use of the three PMN reporting forms would have resulted in regulatory outcomes different from those which actually occurred for a group of PMNs acted on by the Agency.

These objectives were met through a careful review of PMN cases by a senior OTS scientist with substantial experience in the PMN review process. In effect, this process required reconstructing the history of the separate PMN reviews; this entailed a careful reading of the complete file and discussions with numerous OTS personnel to verify the important features, problems and regulatory outcomes of PMNs investigated. The results of this study, though necessarily judgmental, are based on a high level of knowledge and expertise. The results were also corroborated through consultation with other OTS staff.

Reviews were conducted for 14 of the 64 PMNs for which the Agency has informally or formally expressed concerns about possible risks to health or the environment. The actions taken in these cases include TSCA (5)(e) actions, withdrawal or suspension of PMNs due to imminent 5(c) or 5(e) actions, and voluntary actions taken by the submitter following negotiation between the submitter and EPA. An implicit assumption of the study was that the same level of OTS resources would be available for reviews regardless of the PMN form used by submitters.

This study produced a large number of interesting and important results. For the purposes of this analysis the most important is identification of differences in regulatory outcomes given the alternative PMN forms. However, we believe it is useful to briefly describe other areas of important information resulting from the study germane to the entire issue of premanufacture notification.

1. Factors Critical to Identification of Risk

Critical identification factors were defined as specific categories of information that contribute to the Agency's identification of risk leading to regulatory action. In the ICB study, factors were rated as being of low, medium, or high importance in identifying risk with those receiving medium or high ratings considered critical. The following factors were rated critical (the numbers in parentheses indicate in how many of the 14 cases the item was of medium or high importance):*

-- chemical identity (14).

-- impurities identity (<3).

-- description of use (14).

-- hazard warnings (5).

-- number of customers (4).

-- block diagram (<3).

-- occupational exposure - sites controlled by submitter (9).

-- occupational exposure - sites controlled by others (10).

-- release to the environment - sites controlled by others (4).

-- consumer or commercial exposure (5).

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*It is important to note that these ratings are indicators of the relative importance of the various pieces. All of the factors are considered important in that they permit OTS staff to evaluate potential human health and/or environmental effects associated with PMN chemicals.

The Agency's structure/activity relationship and internal health analyses were critical for 11 cases, while in the other three, analyses of impurities of substances generated during use of the PMN substances were critical. Health data submitted with the PMN substances were not the primary grounds for concern in any of the 14 cases in the study, nor was information on release to the environment at sites controlled by the submitter ever the sole factor in Agency decisions concerning possible actions. For eight cases, data from previous PMN reviews were critical factors.

2. Sources of Data on Critical Factors

The three major sources of information used in PMN reviews are: (1) the PMN itself, (2) supplementary information provided by the PMN submitter, and (3) other sources used by OTS personnel during the course of the review. The amount and type of information supplied with a PMN varies in part according to the form used by the submitter.

Of the 14 PMN cases in this sample, the PMN alone provided sufficient data for chemical identification of most class 1 substances; class 2 substances and polymers required additional information, usually from the submitter. (A class 1 substance is one which can be defined by a specific structural formula; class 2 substances cannot.) Adequate use information was received with the PMN in only two cases with all of the other 12 requiring significant additional information from the submitter.

Generally speaking, the PMN forms provided complete information of the following types: class 1 chemical identification, production volume, and hazard warnings. Adequate information was less often provided concerning use category, polymer identification, and occupational exposure at sites controlled by the submitter. PMN data were of little use for providing exposure information on sites controlled by others and consumer/commercial exposures. The PMN forms in this sample were insufficient in and of themselves to evaluate health hazards because the test data and/or risk assessments received with the PMNs were not relevant to the Agency's concerns.

3. Potential for Different Regulatory Outcomes Given Use of Alternative PMN Forms

The likelihood that the Agency will identify and act upon PMN chemicals relies equally on two factors. The first is the information provided in the PMN submissions. The second is the expertise of OTS personnel, i.e., their collective ability to evaluate the degree of potential hazard associated with new chemicals. Because the Agency is confident that the level of in-house expertise is high and that the degree of expertise available is comparable across all individual PMN reviews, the major variable is the quality and quantity of information available to assess the PMN chemicals.

Although information provided in PMN submissions is and will continue to be supplemented by information from submitters during the review period, OTS's ability to identify suspect chemicals is likely to be increasingly dependent upon the information provided in PMN submissions themselves. This situation results from the simple fact that the Agency expects to experience further increases in the number of PMNs submitted,[35] while resources available for reviews will be relatively stable. Thus, the level of effort expended per review will necessarily be reduced, and the amount and quality of information provided in the initial PMN submissions will further increase in importance in enabling OTS to perform its assessments. However, increased OTS expertise and efficiency in evaluating data regarding the potential health effects of PMN chemicals will help to maintain the quality of the analyses.

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[35] The current PMN submission rate of about 900 per year has been projected to increase to a range of 1100 to 1300 in FY 84 (Luttner and Shapiro, 1982).

The different information requirements of the three PMN forms addressed in this analysis (the EPA79, EPA82, and the CMA79 forms) are summarized in Appendix D. Of the three, the EPA79 form requires the most data, while the other two require considerably less information.

The ICB PMN review study found that, of the 14 regulatory actions taken, nine cases were not affected by the particular PMN reporting form used. However, in five cases there was some probability that a different regulatory outcome would have occurred had a different PMN requirement been in place. The probability estimates (i.e., changes in regulatory outcomes) are subjective estimates based on a combination of factors, including the identification of factors of particular importance to risk concerns and the extent to which such factors are likely to be provided given use of alternative PMN forms. The cause(s) of concern, the critical data which led to the action taken, and the probabilities of the same action being taken with other forms for these five cases are presented in Exhibit 7-1.

This analysis of human health impacts therefore focuses on the five PMN substances previously identified by ETD personnel (Farris 1982) for which the use of different PMN reporting forms could have resulted in different regulatory decisions than those that were actually taken.

This chapter addresses the health implications of regulatory actions resulting from the use of different proposed PMN forms. Little discussion of the environmental effects due to alternative forms is provided. Quantitative analysis of toxic effects were not conducted for a number of reasons: (1) for PMN A significant EPA concern about environmental release and subsequent

EXHIBIT VII-1

SUMMARY OF PROBABILITIES FOR DIFFERENT REGULATORY ACTION FOR SELECTED PMNs

Case #	Regulatory Action	Original Form Submitted	Probability Of Action Being Taken With Other Forms And Reason For Difference
PMN A	Withdrawn - 5(e) action was likely due to processor exposure	Submitter's own data package.	EPA79 - Properly filled out would have resulted in same action with 95 percent probability. EPA82 - 75 percent chance of same outcome; reduced exposure data relative to EPA 79. CMA79 - 85 percent chance of same outcome (better processor exposure section than EPA 82).
PMN B	Withdrawn - 5(c) extension likely.	EPA79	EPA82 - 80 percent chance of same outcome; insufficient processor/consumer and other chemical information. CMA79 - 85 percent chance of same outcome; lack of some chemical identity information.
PMN C	Label change.	Submitter's Own Data package (very detailed)	EPA79 - 80 percent chance of same outcome; form requires less detailed exposure information than was submitted. EPA82 - 50 percent chance of same outcome; reduced consumer/commercial exposure requirements. CMA79 - 40 percent chance; lower consumer/commercial exposure data requirements.
PMN D	MSDS Change.	EPA79	EPA82 - Same action would have occurred. CMA79 - 50 percent since decomposition product identity or original MSDS is optional; greater than or equal to 95 percent if these data were submitted (somewhat unlikely).
PMN E	MSDS Change.	EPA79	EPA82 - Same action would have occurred. CMA79 - 80 percent chance of same outcome; lack of block diagram and reduced likelihood of MSDS.

Source: Farris 1982.

toxicity and persistence existed. However, the lack of test data precluded quantitative assessment of the problem. Analysis of analogues showed that PMN A may have presented a moderate to severe hazard to aquatic life and that bio-concentration may be an important factor. EPA requested ecological testing be performed and the submitter withdrew the PMN. (2) PMN B was expected to be persistent in the aquatic environment, and to possess aquatic toxicity. In this case as well, analogues were used to predict problems with the PMN and only speculative conclusions could be reached. The PMN was withdrawn by the submitter; (3) for PMNs C, D, and E, there were no problems identified concerning environmental release, toxicity, persistence, or bio-concentration. All three PMNs were dropped from review after voluntary actions were taken by the submitters.

In the discussion that follows we briefly outline the regulatory history of the substances in question, analyze the conditions under which human exposure or environmental damage might occur, review the toxic properties of the substance and, where possible, develop rough estimates of the health impacts that could have resulted from alternative regulatory or voluntary actions.

C. CASE STUDIES

1. PMN A

a. Regulatory History

This PMN substance was intended for use as a plasticizer in the production of consumer products made from polyvinyl chloride plastic (PVC). The manufacturer stated that although initial production runs of tens of thousands of kilograms were anticipated, commercial success of the product might increase demand to as much as several million kilograms per year. The PMN was submitted on none of the three forms under consideration but was accompanied by an information package designed by the submitter. The major concerns expressed by EPA were primarily due to the large production volume and resulting potential for occupational and consumer exposures. The Agency conducted several extensive reviews of the possible health effects of the PMN substance and estimated the likely extent of exposure. Eventually a decision was made to draft a 5(e) order, requesting more information on potential chronic toxic effects. The manufacturer withdrew the PMN the day the order was issued.

b. Human Exposure and Environmental Release

The PMN substance was to have been produced in a modern, highly-automated, dedicated facility in an enclosed process. The two steps in the production processes were to be performed in very large sealed vessels. The EPA exposure assessment study estimated that no more than 12 workers would be exposed to the PMN substance during its synthesis or packaging. They would be exposed to the pure liquid material primarily through the dermal route.

The compounding of PVC using the PMN substance was to be carried out at facilities not controlled by the manufacturer. The compounding would involve the mechanical mixing of the PMN substance with raw PVC resin and other additives and would occur at 20-30 facilities owned by the major customers of the PMN manufacturer. EPA estimated that 500-1000 workers would be exposed dermally to resin formulations containing the PMN substance, and that air exposure levels (inhalation) would be on the order of 0.1-5.0 mg/m^3.

The fabrication of PVC products containing the PMN substance would take place at numerous small facilities specializing in the manufacture of one or more specific types of products. EPA estimated that 15 to 30 thousand workers would be exposed to the PMN substance during fabrication. Exposure levels were expected to be about the same as for formulation.

The PMN substance was not expected to decompose completely during fabrication or to react with the PVC to become immobilized in the final products. Some, if not the bulk, of the PMN substance would be available to cause exposure to the consumers of PVC products. EPA estimated that as many as 100 million persons were potentially at risk of exposure. EPA calculated, using typical values for the proportion of the PMN substance found in products and the expected extent of dermal exposure, that the average consumer could be expected to absorb as much as 2.6×10^{-6} mg/day of the PMN substance.

It was also estimated that up to 2-4% of the PMN substance could be released into the environment per year. Some release to publicly owned treatment works or the Mississippi River was also expected. A lack of environmental test data prevented any further analysis of environmental release or exposure.

c. Toxic Properties

Because the PMN substance was closely related to a number of other widely used plasticizers, some data were available which were useful in assessing the possible toxic effects of the PMN substance. The acute toxicity of this family of substances was generally quite low. Previous industrial experience with similiar substances indicated that dermal exposure could cause skin irritation, although test data submitted for the PMN substance itself failed to find evidence of skin irritation in animals.

The PMN substance was expected to be metabolized very rapidly in the body to mainly innocuous compounds although one scientist expressed mild concern that one of the metabolites was similar to a prostaglandin precursor and that ingestion of the PMN substance could disrupt prostaglandin metabolism and cause unspecified metabolic and physiological disturbances.

Several members of the family of compounds to which the PMN substance belongs have been shown to possess carcinogenic activity. Thus, one of the major concerns expressed early in EPA's evaluation of the toxicology of this compound was the potential for carcinogenicity. However, a review of the literature indicated that the nearest analogue to the PMN substance which has been tested for carcinogenic activity has not been demonstrated to cause cancer in animals. Five out of six long-term studies of a relatively close analogue to the PMN substance showed no detectable carcinogenic activity. Only one study indicated an increase in tumor incidence in mice exposed to the substance, and in that study, the elevation in tumor incidence was not statistically significant. No other close analogues of the PMN substance have been tested for carcinogenicity. At the end of the Agency's review, possible carcinogenicity was still of concern, but the level of this concern was somewhat lower than it had been originally.

Little data are available on the mutagenic properties of the PMN substance, but the close analogue was found not to be a mutagen in standard bacterial assays.

d. Health Implications of Alternative Regulatory Actions

The ETD analysis of alternative reporting forms suggested that two of the reporting forms under consideration, the CMA79 form and the EPA82 form, might not have supplied adequate data on the duration and intensity of processor exposure to alert EPA to the potential health hazards of the PMN substance. ETD staff estimated that there would be approximately a 15 percent and 25 percent chance, respectively, that EPA would have allowed the PMN substance to be produced had these forms been used.

We would suspect that the major immediate effects of allowing this substance to be made would have been the occurrence of increased exposures, possibly producing some number of cases of dermatitis among the workers exposed during the production of the PMN substance and during the formulation and the fabrication of PVC resin. The number and severity of these effects cannot be estimated from the available data.

While it is possible that chronic effects other than cancer might occur, (considering the number of workers exposed, such effects might constitute a substantial portion of the total health impact), the number of likely cases of such effects also cannot be estimated.

The majority of the available data suggest that the PMN substance is not a carcinogen. It is not unlikely, therefore, that the PMN substance would in fact not cause any measurable increase in cancer incidence among exposed workers or consumers. However, if one extrapolated from the 95 percent upper confidence limit for the highest dose "negative" animal test (assuming that the test gave a false negative result), rough calculations[36] indicate that each year of use of the PMN substance would be expected to produce about 9 cases of cancer among all of the exposed workers over their lifetimes. About 8.7 would be expected to occur among fabricators, 0.3 among formulators, and less than 0.02 among the producers of the PMN substance. No cases (less than 0.001 cases/year) would be expected to occur among consumers. More than anything else these estimates spell out the potential health implications of the high occupational exposures, and illustrate the reason for EPA's concern.

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[36] This assessment assumes a linear dose-response extrapolation from the highest dose "negative" animal test result.

The question of what proportion of these possible health effects were prevented by EPA's action (and might not have been prevented by the CMA and EPA82 forms) is very difficult to answer. The major substitutes for this material are very close structural analogues, which would be expected to have very similar toxicological properties to the PMN substance. Since the feedstock materials for these analogues are becoming more expensive (this being the major reason for the introduction of the PMN substance), it is possible that EPA's action resulted in a slight decrease in the total amount of plasticizers of this type consumed and a corresponding slight decrease in the health effects associated with this class of materials (primarily skin irritation).

2. PMN B

a. Regulatory History

This substance is also a plasticizer used in the production of PVC coatings and floor tiles. It is a low molecular weight polymer. The manufacturer estimated that as much as a few hundred thousand pounds of the PMN substance would be manufactured in the third year of production.

The PMN was submitted on the EPA79 form although not all of the information requested in that form was supplied. Again, one of the major concerns expressed by EPA had to do with the potentially large production volume and resulting exposures. In addition, ambiguities about the actual chemical composition of the PMN substance prompted EPA to actively solicit more data from the manufacturer and to become concerned about the potential for possible adverse health effects and possible effects of exposure to two major chemical constituents of the PMN substance. When it became clear that EPA intended to extend the review period, the manufacturer withdrew the PMN.

b. Human Exposure and Environmental Release

The PMN substance was to be produced by a standard reaction procedure in a closed reaction vessel and shipped in drums to processing facilities. Little other information was supplied by the manufacturer about the production process, the use of protective equipment, or expected levels of exposure. EPA estimated that fewer than 10 workers would be exposed during production and that as many as 100 to 1000 could be exposed during processing and application of the substance. An undetermined number of others (floor installers and consumers) would be expected to experience some exposure as well. The Agency noted that measured occupational exposure levels to similar substances in similar applications had been on the order of 10^{-4} mg/m^3 in air during production and processing. In rooms tiled with products containing the PMN substances, consumer exposures were expected to be much lower.

Environmental releases were expected to be on the order of a few kilograms/year to air, hundreds of kilograms/year to landfills and as much as several thousand kilograms per year to publicly owned water treatment works. These releases were thought to pose a mild toxic hazard to aquatic organisms. It was also known, however, that certain constituents of the PMN substance had potential to be bioconcentrated and could also pose a threat to human health. Since environmental test data were not available for the PMN substance, analysis of environmental effects was not possible.

c. Toxic Properties

The original PMN filing gave very little information as to the actual chemical composition of the PMN substance, describing it merely as a low molecular weight polymer. Subsequent discussion with the manufacturer disclosed the fact that the material, while it did contain some relatively high molecular weight material, was composed, on a molar basis, primarily of low molecular weight oligomers.

In particular, analysis suggested that the PMN substance could contain significant amounts of low molecular weight components and unreacted feedstocks. Structural analogues to several of these substances have been observed to display a wide range of toxic effects, most notably on the reproductive system. Closely related substances of one component, for example, have been demonstrated to cause impaired fertility, decreased fetal weight, dominant lethal mutations and teratogenic effects in experimental animals. A similar situation is seen for the second component, with analogue compounds closely related to the PMN substance having been found to be teratogenic in laboratory animals and to cause decreased fetal weight, dominant lethal mutations and sister chromatid exchange in animals. Evidence for effects in humans is slight, however, and the recent laboratory studies suggest that the majority of the effects seen in animals occur only at dose levels far higher than those likely to be experienced by humans.

d. Health Implications of Alternative Regulatory Actions

The ICB analysis estimates that, owing to differences in the amount of data requested concerning the chemical identity and consumer and producer exposure to the PMN product, there is about a 20 percent chance that the Agency would not have taken action on this substance if the EPA82 form had been in use and about a 15 percent chance that they would not have taken action if the CMA form were in use. If EPA had not taken any action, the PMN substance could have been produced, human exposure would have taken place, and adverse health effects similar to those described above might have occurred. It is not possible, because of the lack of data concerning exposure levels and uncertainty about human toxicity, for the reproductive effects to be estimated quantitatively. Based on analyses of the toxicological literature, however, we would not have expected the number or severity of effects to have been very great and it is possible that no detectable adverse health effect would have occurred as a result of the PMN substance being produced.

As in the previous case, the potential magnitude of the net health impacts associated with the decision not to produce this substance is reduced by the fact that some of the substitutes for this chemical are closely-related chemically (and toxicologically). In this case, however, there appear to be some substitutes commonly in use which are less likely to be harmful. Thus, it is likely that the prevention of the production of the PMN substance has resulted in positive health impacts is somewhat greater than in the previous case.

3. PMN C

a. Regulatory History

PMN C is a catalyst used to process photographic prints. The notice of intent to import did not make use of any of the alternative PMN forms under consideration. Information on consumer exposures contained in the notice, which would not have been required by either the EPA82 form or the CMA form, alerted EPA to the possibility of adverse health effects among consumers. The Agency suggested an alteration in the product label which would tell consumers that gloves should be worn during use. The importer agreed and commenced to import the chemical.

b. Human Exposure and Environmental Release

Since the chemical is imported, occupational exposures during manufacture are not of concern in this case. The substance is imported in essentially pure form in bags. The substance is a fine powder and it must be assumed that there is considerable potential for airborne dust formation. When received by the importers, the substance is dissolved in warm water in open vats. Gloves, aprons and masks are worn by the workers performing this task. The importer then sells the concentrated solution to consumers who dilute it further for use. In the initial dilution step, workers are exposed for 50 person-hours per year to both airborne dust and water solution of the substance. During packaging, six workers are exposed for a total of 900 person-hours per year.

A relatively large number of consumers (professional and some amateur photographers) are expected to be exposed to the PMN substance. The Agency analysis of consumer and environmental exposures estimates that between 3,200 and 9,600 persons will use the material each year. Each user is expected to use the material between 50 and 150 times per year for an average of 15 minutes per use, although the actual length of exposure (arising primarily from spills and splashes) will be much shorter. All consumer exposures are expected to be dermal, and Agency scientists believe that, at most, 10 percent of the PMN substance would be absorbed through the skin during a 5-minute exposure to either the of the PMN solutions.

Some concern was expressed over the aquatic toxicity of the substance, but it is clear that, owing to the small volume of material imported and the small concentrations of material in the final product, even a very small dilution volume would be sufficient to lower the concentration below levels toxic to aquatic plants, fish, and sewage treatment organisms. No significant environmental exposure or release was expected for this chemical and concern was low.

c. Toxic Properties

The only toxicology data available concerning the PMN substance itself were results of tests conducted by the manufacturer and submitted with the PMN. These results indicated that the PMN substance was a relatively weak acute toxin in rats and produced "slight" skin irritation and "mild" eye irritation in standard tests in rabbits. These results are not particularly relevant to the assessment of potential chronic effects, but they do suggest that, under the stated conditions of occupational and consumer exposure, few acute toxic effects can be expected. The acute studies showed the liver and pancreas to be the major target organs.

No data were available in the file about the chronic toxic effects of the PMN substance other than a statement that similar substances, by mimicking the structure of DNA bases, may cause mutations and elevated cancer risks. There was also evidence that chronic exposure could cause liver injury, making the liver a potential site for tumor formation. A close analogue was shown to be an antithyroid agent.

Since the data are so inconclusive (when not contradictory), it does not appear to us to be appropriate to attempt any quantitative assessments of the cancer risks associated with exposure due to the PMN substance, or even to maintain that exposure to the substance would produce any increase (or decrease) in cancer risk among exposed individuals. Instead, the following discussion will be limited to the other chronic effects (described above) of exposure to the PMN chemical.

d. Health Implications of Alternative Regulatory Actions

The ICB analysis suggests that the information supplied by the manufacturers which caused EPA to be concerned with the potential health effects from consumer exposures would probably not have been included in either the CMA or EPA82 forms. Without specific exposure information, EPA might not have identified consumer exposure as an important potential health problem and probably would not have suggested the labeling changes which were voluntarily accepted by the manufacturer. Users would not have been warned to wear gloves while handling or using the product and increased dermal exposure would have resulted. ETD estimates that with the EPA79 form in use, there would have been about an 80 percent chance that some form of warning would have been supplied, while with the EPA82 and CMA79 forms, the chance that any regulatory concern would have been expressed would be about 50 percent and 40 percent respectively.

In order to assess the potential hazards from consumer exposures, it was necessary to estimate the amount of PMN substance that would be absorbed during a typical exposure.[37J] We assumed that typical exposure would involve contact (due to a splash or spill) with either the concentrated or diluted solution; and that, in either case, the total amount of PMN substance involved was <5.0 mg. We assumed that the length of contact with the skin is 15 minutes, and that during this time as much as 30 percent of PMN substance would be absorbed.

The doses involved are below what is commonly believed to be the threshold for chronic toxic effects. However, from a physiological standpoint, the upper end of the dose range is very close to toxic levels. It

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[37J] This analysis is based on the known toxicological properties of any of the PMN substances. The analysis may appear somewhat cryptic because of the need to preserve the confidentiality of more specific data relating to the chemical identity and toxic properties of the PMN substance.

is likely that some small proportion of the exposed population would be sufficiently susceptible to experience some adverse effects, if only changes in physiological state (abnormal levels of enzymes in the blood, for example). As a rough estimate (more refined estimates are not possible, given our state of knowledge), we would expect that possibly 1-10 percent of those individuals receiving high exposure could experience some symptoms of toxicity.

The effects of exposure could range from asymptomatic slight changes in indices of liver function, to severe liver toxicity characterized by gastrointestinal upsets, malaise and possibly fever and headaches. Changes in skin pigmentation might occur, along with the development of brittle fingernails and increased dental caries. Fatal outcomes are unlikely since the association between exposure and symptoms is likely to be discovered before very severe effects occur.

It is difficult to estimate the effect of the warning label on user behavior or the extent to which exposures would be reduced. Without the warning, it is likely that some users would wear gloves anyway. With the warning, many users might still not take precaution to reduce dermal contact. As an upper limit on the number of cases of toxic effects that could be avoided, we will assume that the warning would prevent all high exposures. If it were assumed that, without the label, 10 percent of the 3200 to 9600 users would experience high exposures (and 1-10% of these would experience adverse effects), this implies that failure to label would result in between 3.2 and 96 cases of adverse health effects as described above among regular users of the PMN substance at any point in time. The upper limit is probably on overestimate, because a large number of users implies a lower average exposure. Assumptions about a greater degree of care among users without the warning label, or less than 100 percent efficiency of the warning in reducing high exposures would correspondingly reduce the estimate of the reduction in adverse health effects. We think it would not be unreasonable to assume that without the warning label 25 percent of users would wear gloves, while with the warning label 75 percent would wear gloves. This would imply that the failure of label that might have resulted from insufficient PMN data, could have resulted in between 0 and 48 cases of toxic effects, some of which, perhaps the majority, would be asymptomatic changes in the physiologic state of the exposed individuals. Greater or less efficacy of the warning label in reducing high exposures would result in corresponding increases or decreases to the number of individuals, with an upper limit of 96 cases.

4. PMN D

a. Regulatory History

This PMN substance is a photographic chemical which was to be imported in small amounts to be used as an ingredient in an "instant" film cartridge. The PMN was submitted on the EPA79 form, and the principal concern centered on the presence of an unavoidable trace contaminant, a decomposition product of the PMN chemical. This substance is a known animal carcinogen. In addition, the PMN substance itself was known to be a severe eye irritant and capable of causing burns if dermal contact occurred.

Because of the extremely small volume of substance that was to be imported, EPA did not feel that major regulatory action was required. The Agency did, however, recommend that the Material Safety Data Sheet (MSDS) be revised and the importer agreed to do so. The revised MSDS included mention of the carcinogenic properties of the trace impurity, emphasized the danger of allowing dermal or eye contact and recommended local ventilation practices to be used when handling the substance. EPA agreed to allow commencement of importation.

b. Human Exposure and Environmental Release

EPA estimated that a total of approximately 80 workers would be exposed to the PMN substance. Exposure levels in air were estimated to be between zero and 1 mg/m^3. The manufacturer stated that it was standard procedure for workers involved in the production of similar products to wear gloves, goggles, breathing masks and impervious clothing, so that effective exposure levels, not counting spills or other accidents, would be much lower than the estimated ambient air levels. Because of the low volume to be imported, environmental release of the substance (into publicly owned treatment works), was not thought to present any danger to humans or other organisms.

c. Toxic Properties

The PMN substance itself is a strong acid, and as previously stated, could be expected to cause eye irritation at high vapor concentrations and skin burns if dermal contact with a concentrated solution were to occur. The use of the personal protective devices mentioned above and proper work practices should minimize the incidence of such occurrences, however.

The trace impurity (no mention was made of its concentration in the PMN substance) has been unambiguously demonstrated to be a potent animal carcinogen, although no human epidemiological evidence is available.

d. Health Implications of Alternative Regulatory Actions

The ICB analysis suggests that if the EPA82 form had been used for this substance, there would have been approximately a 30 percent chance that no concerns would have been raised and the substance would have been cleared for import without any revision of the MSDS. If the CMA79 form were used, it was estimated that there would have been approximately a 50 percent chance that no action would have been taken. This is because neither of these forms would have required submitters to supply information regarding the identity of the impurity which was the major cause of concern.

It is probable that the revision in the MSDS provoked only marginal changes in practices and procedures used when handling this material. Even without the changes, the material would have been labeled as corrosive and irritating and it appears that the firm in question already had in place a reasonably aggressive policy on the use of personal protective devices. Nonetheless, the more explicit warnings on the revised MSDS, and the warnings about the possible carcinogenicity of the impurity might have influenced workers and supervisors to be more careful and could have prevented a few cases of skin or eye injury per year. It is not clear, however, that any significant number of cancers would have been prevented. Rough calculations indicate that even at the estimated maximum exposure levels, (assuming no protective effects from personal protective equipment), exposure to the impurity in the PMN substance would have resulted in less than 10^{-4} cases of cancer among all of the workers per year of exposure.[38J]

In this case, (like all cases other than withdrawal and suspensions) the issue of the health effects of potential substitutes does not arise because EPA action did not directly result in chemical substitution.

[38J] This calculation is based on a linear dose-response extrapolation, on the basis of lifetime average daily dose, from the lowest-dose positive animal bioassay, assuming worker exposure levels of 1 mg/m^3 for the entire 8-hour working day for one year of exposure.

5. PMN E

a. Regulatory History

The PMN substance in this case is a salt of the acid that constituted PMN D. Unlike the previous case, however, this substance was to be manufactured in the United States rather than imported. The PMN substance appeared to be intended for use in the same product as PMN D and may in fact have been intended to be substituted for it.

The PMN was submitted on the EPA79 form. The health concerns were similar to those concerning PMN D. Although the PMN substance would have been a less severe skin and eye irritant and would not decompose to form the carcinogenic by-product, it would have been manufactured from that substance and would contain small amounts as an impurity. EPA again did not take direct regulatory action, but allowed manufacture to commence after the submitter made voluntary revisions to the MSDS. The revisions were almost identical to those made for PMN D.

b. Human Exposure and Environmental Release

Again, approximately 80 workers would have been exposed to the PMN substance. Precise exposure levels to the PMN substance were not known, but probably would have been similar to those for PMN D. Exposure to the carcinogenic starting material (the impurity in PMN D) would be higher during manufacture, however. Personal protective devices were to be employed during the production and use of the material. Environmental release was not expected to present a problem and consumer exposures were not expected to be significant.

c. Toxic Properties

The acute toxic properties of the PMN substance (eye irritation and the ability to cause skin burns) would be expected to be less for this substance than for PMN D due to the neutralization of the acid. The magnitude of the carcinogenic hazard posed by the PMN substance would be proportional to the levels of exposure to the starting material during manufacture. The hazard could easily be greater than that posed by the use of PMN D.

d. Health Implications of Alternative Regulatory Action

The ETD analysis estimates that there would have been a 20 percent chance that EPA would not have recommended changes in the MSDS had the CMA79 form been used. Had this occurred, the result probably would have been similar to that for PMN D, namely, the occurrence of at most a few more cases of skin or eye irritation and a negligible increase in the cancer risk to exposed workers. Both the EPA forms would have "caught" this chemical.

The implications of the fact that PMN E may be a partial or complete substitute for PMN D are not clear. If either chemical is used to the exclusion of the other, then it would not be proper to attribute the risk reduction for both chemicals to the PMN program or to the use of one or another of the PMN forms. Also, to the extent that PMN E is used in preference to PMN D, net health risks would be increased because the synthesis of PMN E involves the use of the highly carcinogenic starting material, while the importation of PMN D does not involve such risks, at least at facilities under the jurisdiction of TSCA. It is likely that the PMN program was influential in the producer's decision to consider the use of the less hazardous substance. Thus any decrease in exposure to PMN E can probably be attributed to the PMN program.

D. SUMMARY OF ANALYSIS OF ALTERNATIVE PMN FORMS

Exhibit 7-2 summarizes the results of this analysis. In two of the cases that were analyzed (PMNs A and B), information submitted on non-standard PMN

EXHIBIT VII-2

SUMMARY OF RESULTS

PMN Number	Result of Agency Concern	Probability Not Caught With Other Form	Net Health Effect
A	Withdrawn	25% EPA82 15% CMA79	Few short-term benefits -- substitutes present roughly comparable hazards -- possible long-term benefits (see text)
B	Withdrawn	15% CMA79 20% EPA82	Few short-term benefits -- substitutes present rougly comparable hazards -- possible long-term benefits (see text)
C	Label/MSDS Change	50% EPA82 60% CMA79	Up to 50 cases of chronic toxicity avoided among regular users of the PMN substance
D	Label/MSDS Change	30% EPA82 50% CMA79	Up to 10 skin or eye irritations per year could occur
E	Label/MSDS Change	20% CMA79 0% EPA82	Up to 10 skin or eye irritations per year could occur

forms eventually led to such grave risk concerns on the part of EPA that the manufacturer withdrew the PMNs. In each case, ICB believes that there is some chance (15-25 percent) that the use of either the EPA82 or CMA form would have allowed these substances to be introduced without regulatory concerns, while the EPA79 form would have almost certainly "caught" the two substances.

For PMNs C and D, ICB judged that there was a substantial likelihood (30-60 percent) that the CMA79 and EPA82 forms would not have provoked sufficient Agency concern to have resulted in the labeling or MSDS changes which actually occurred, while the EPA79 form was almost certain to have provided sufficient information. For PMN E, only the CMA form was considered to have the potential (20 percent probability) for not supplying sufficient data.

In three of the five cases (PMNs A, B, and C), differences in the amount of data concerning exposures to processors or consumers requested by the various forms could have resulted in different levels of Agency concern and correspondingly different Agency actions. Ambiguities concerning the exact chemical identity of PMN B also contributed to potential differences in regulatory outcomes between the three PMN forms. In the case of PMN D, two of the forms (EPA82 and CMA79) might not have alerted EPA to the identity of a potentially hazardous impurity in the PMN substance; while in the case of PMN E, the CMA form, by virtue of not requiring a block diagram, might have misled the agency into assuming that this substance was manufactured from PMN D, when in fact it was not.

Based on ICB's assessment, it would appear that the EPA79 form was more likely to provide sufficient information for regulatory decisions then either the EPA82 or CMA forms.

The magnitudes of the benefits of having sufficient information to make the correct choices seem to be rather modest for the five cases studied. For the two cases which were voluntarily withdrawn, short-term benefits are expected to be slight (if any existed) because other chemicals with similar hazardous properties are likely to be substituted for the PMN chemicals. However, there may be long-term benefits of discouraging the introduction of hazardous new chemicals, even where they may not pose a substantially greater risk than the chemicals they would replace. The pursuit of this policy will ultimately result in significant decreases in the aggregate risks associated with new chemical products by categorically encouraging the introduction of less hazardous chemicals.

For the three cases where labeling and MSDS changes were made, benefits take the form of reduced exposure resulting from safer handling practices. For PMN C, the photographic chemical with considerable potential for consumer exposure, as many as 50 cases of chronic toxicity, many of them perhaps substantial in severity, were avoided. In the case of the two substances used to produce instant film cartridges, changes in the MSDS may have resulted in the avoidance of some small number (probably less than 10) cases per year of skin or eye irritation due to improper handling practices.

It should be noted that the number of cases analyzed here is too small to provide a statistically valid sample of results upon which to give definitive quantitative estimates of the benefits of one or another PMN form. Potential benefits could be much greater where a PMN is filed for a substance with different properties (more severe toxic effect) than close substitutes, or where a hazardous chemical was introduced for a "new" use (no close substitutes were available). The potential benefits in these situations may be very great.

It should also be reiterated that these cases do not provide an estimate of the total benefits of the PMN program. The cases analyzed here are marginal cases or close calls; in the case of obviously hazardous chemicals we would expect that any of the three forms under consideration would supply adequate data to enable EPA to recognize the hazards associated with their introduction. Also not analyzed here is the deterrent effect of the PMN program - i.e., that aspect which has probably discouraged manufacturers from submitting some new products, which they know to be hazardous, to the Agency for review in the PMN process. It is probable that this deterrent effect constitutes the major portion of the health benefits of the PMN program.

CHAPTER VIII

IMPACT OF THE FINAL FORM

In the previous seven chapters the costs and benefits of three alternative PMN information requirements were determined and compared. The results of this analysis show that the substantially reduced reporting burden represented by the CMA79 and EPA82 forms would in some cases result in unacceptable PMN review decisions due to the lack of important data and information. That is, reductions in risk that have occurred under the interim policy would not occur 10-35% of the time if either of these two forms were adopted as final forms. For this reason the Agency decided to amend the EPA82 form in such a manner that it could be reasonably certain that the FINAL form would result in the same PMN-specific outcomes, retrospectively, as have occurred since the program began.

A. DEVELOPMENT OF A FINAL FORM

This refinement of the form is simply the last adjustment in a long series of adjustments that began in late 1978. At that time the Office of Toxic Substances had been focusing on developing the Chemical Substance Inventory as required by section 8(b) of TSCA. Because the statute mandated that the PMN program begin shortly after the inventory closed, OTS developed a form designed to meet the statutory requirements and that would allow a thorough risk analysis of the new chemical within the ninety day PMN review period. The economic analysis of this form (ADL 1978) suggested that serious economic consequences might result from its promulgation. However, the Agency proposed the use of this particular form in a rule published in January 1979.

The industry response was sharp. The major criticisms were that the form was overly burdensome and asked for information that was both inaccessible to the submitter and beyond the requirements of the statute. In response the Agency published amended interim guidance in May 1979. This amended interim guidance formed the core of the PMN policy for the next three and a half years.

In October 1979 the Agency proposed another PMN form that was significantly less burdensome than the January 1979 form. (This form was the baseline of this analysis.) Even this considerably less burdensome form was considered overly costly by the industry, which provided economic arguments in an attempt to prove that the form cost would destroy chemical innovation (CMA 1981). Some anecdotal evidence also suggested that certain R&D programs were temporarily ceasing new chemical innovation activities as the industry waited to see how the PMN program evolved (ICF 1980).

As previously stated, the Agency chose to rely on the interim policy for operating purposes for over three years. Under the interim guidance more than 1500 PMNs have been submitted over the past three years. As discussed in the previous chapters of this report, the Agency has learned much about both what is required to determine the risks posed by a new chemical and what kinds of questions typically trigger concerns during the Agency's review.

This experience with the interim policy allowed the Agency to make substantial revisions to the proposed form with the confidence that the revisions would not result in increased risks from new chemicals. Indeed, over the past three years many amendments to the EPA79 form were considered internally and after careful analysis and long debate accepted or rejected. The EPA82 form, a draft document prepared solely for internal for OTS analysis, represented the culmination of this activity as of the spring of 1982.

There are many reasons why the Agency chose to amend the EPA82 form, i.e., to develop the FINAL form. As described in Chapter IV, the strategy behind the EPA82 form was to require completion of a short form which would request only that information needed for initial review, and to rely on voluntary data submissions and, if necessary, section 5(e) authority to collect additional information when the information provided for initial review was insufficient. Analysis performed in support of this RIA suggested that some items had been left out that were needed for initial review and, most importantly, some items that had been critical to identifying some problem chemicals were not included. Thus, with the EPA82 form it was more likely that a problem chemical could go through initial review without being recognized as hazardous. The FINAL form, by adding certain items, insured that potential problem chemicals would be identified during initial review. The FINAL form was also analyzed from the standpoint of its economic impact with the goal of reducing the reporting burden as much as possible, again without jeopardizing the Agency's ability to identify problem chemicals.

In this chapter the contents of the FINAL form are described and its costs and benefits are discussed. The FINAL form analysis has been prepared to parallel the previously presented analyses of the EPA79, CMA79, and EPA82 forms. The analysis concludes that the FINAL form will cost industry between \$100,000 and \$1,600,000 annually more than the EPA82 form. In return for this relatively small increase in costs, the Agency can be confident that it will be able to identify problem chemicals and obtain reductions in risk in the future consistent with those obtained in the first three years of the program's existence.

B. ANALYSIS OF COSTS OF THE FINAL FORM

The information sought under the FINAL form includes: submitter's identity; chemical name, identity, and molecular structure; simplified production and marketing data; simplified process diagram; and simplified worker exposure, release, and disposal estimates, and less specific information about sites not controlled by the submitter (data comparisons are relative to the EPA79 form). A copy of the FINAL form is presented in Appendix G.

1. Differences Between the FINAL Form and EPA79 Form

Differences between the FINAL form and the EPA79 form are highlighted below. These differences are illustrated in detail in Appendix D.

a. Submitter's Information

The FINAL form requires the name of the person filing the notice, the technical contact, the identifying number of any prenotice communication and any test market exemption or bonafide request information. It does not request the name of the parent company or the expected commencement of manufacture date.

b. Chemical Identity

The FINAL form requires basically the same information as the EPA79 form with the addition of 1) molecular weight distribution and distribution of low-weight species for polymers, and 2) specific byproduct information.

c. Production and Marketing Data

EPA does not request maximum and minimum production volumes for each of the first three years of production. Rather, the first twelve month production volume and maximum production for any 12 month period during the first three years are requested. Information is required on the intended categories of use of the chemical by function and application. Estimates of the number of customers for each category of use and descriptions of categories not contributing to production estimates, but actively explored, are not required. Formulation percent is specifically requested. Also sought is whether the chemical will be used in industrial, commercial, consumer, or site-limited situations.

d. Other General Information

Sections on transport methods and detection methods are eliminated. Space for providing a risk assessment is eliminated since EPA interprets this as a health and safety study which would be received as part of other data.

e. Industrial Sites Controlled by Submitter

EPA requires identity of sites, number of sites, amount manufactured or processed, points of release of the new chemical substance, and identity and weight of feedstock materials. Items not required include: reactions and side reactions for each chemical conversion, identification and weight of all materials leaving each operation and conversion, methods of transfer, whether the system is open or closed to the workplace, and points of release of byproducts.

EPA would not require submitters to identify operations in which workers may be exposed and routes of exposure but instead to describe activities in which workers may be exposed to the new substance.

Also, a list of substances, other than the new substance, that are likely to occur in the workplace would not be required. This information would be obtained during detailed review if needed.

For environmental releases, EPA would require estimates of the amount of new substance released, the media of release, and the control technology on a release-point specific basis.

f. Industrial Sites Controlled by Others

The FINAL form requests a general discussion of occupational exposure and environmental release at sites controlled by others, including submission of information on the number of workers exposed, exposure duration periods, and an estimate of the number of sites at which such operations will occur.

g. Consumer and Commercial Use Exposure

No consumer and commercial use exposure information would be required, but the submitter would have the option of providing demographic data. In the use section, the submitter would check a box if either commercial or consumer use was expected.

h. List of Attachments and Federal Register Notice

All tests and other data in the submitters possession would be required, and other requirements for notice attachments remain the same. A Federal Register notice would not be required.

2. Form-Filing Costs for the FINAL Form

The FINAL Form represents a decrease in hours and costs compared to the EPA79 form and a slight increase relative to the CMA79 and EPA82 proposals. Using the labor rates discussed in Chapter III and hours estimates necessary to complete the FINAL form as shown in Exhibit VIII-1, the cost to complete all mandatory sections of the FINAL form is between $1,300 and $7,500. Assuming 900 PMNs per year, the total annual cost of the mandatory portion of the FINAL form is $1,170,000-6,750,000.

The differences between the FINAL form and the EPA82 form are mostly minor additions and clarifications. The EPA82 form requests information on chemical identity, production and marketing plans, and exposure and release at sites controlled by the submitter, and attachments. The FINAL form simplified the production and marketing, exposure and release, and attachments section. The additional information requirements are: characterize occupational exposure in terms of worker activities; match the release points in the process diagram with the environmental release information; and provide general information about exposure and release at sites not controlled by the submitter. Exhibit VIII-1 summarizes the completion hour estimates for the FINAL form.

3. Confidentiality Cost for the Proposed FINAL Form Requirements

The FINAL form requires the same generic information as the EPA82 form -- generic chemical identity and generic chemical use. Substantiation is not required for these items. The costs to provide these items were previously estimated as $56 and $13 per PMN respectively. Substantiation of confidentiality claims only occurs when a Freedom of Information Act request is made.

In other words, an expected cost of $69 is always being incurred regardless of the PMN form used. Because FOIA requests occur 17.7 percent of the time, other confidentiality costs of $1686 ($1755 less $69) occur that often so that the expected value per PMN of other confidentiality costs is $298 ($1686 x .177). Therefore, confidentiality costs per submission equal $367 ($69 + $298). For 900 PMNs, total annual confidentiality costs for the FINAL form are about $330,300.

EXHIBIT VIII-1
ESTIMATED LABOR REQUIREMENTS FOR FINAL FORM

		CLERICAL	TECHNICAL	MANAGERIAL
I.	General Information[5]	2-6		
A.	Submitter Identification			1-8[2]
B.	Chemical Identity			
1.	Class 1 or 2		1-4[3]	
2.	Polymers		1-6[3]	
3.	Impurities		1-6	
4.	Trade Identification		0-1	
5.	Byproducts		0-1	
C.	Generic Names		0-4	0-1
D.	Production and Marketing Data			1-2
1.	Production Volume		1-4	
2.	Category of Use		1-8	
3.	Hazard Information		1-1	
II.	Human Exposure and Environmental Release[5]	2-9		2-8
A.	Industrial Sites Controlled by the Submitter			
1.	Operations description			
	- type and duration		1-2	
	- process diagram		1-10	
2.	Occupational exposure		2-15	
3.	Environmental release		1-8	
B.	Sites Controlled by Others		0-17	
IV.	List of Attachments[5],[6]	2-6		
A.	Notice Form Sections[1]		--	
B.	Environmental Fate data[6]			
C.	Health and Environmental[6] Effects Data		8-40	2-8
TOTAL		6-21	18-123[4]	6-27

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[1] Included in above estimates.

[2] Included legal review time.

[3] Only one of these two sections would be completed.

[4] Counts polymer chemical identity section, not Class 1 or 2.

[5] These titles match EPA79 headings for ease of comparison. Actual headings in non-EPA79 Forms differ. See Appendix G for copies of all forms.

[6] Estimate of 8-40 hours and 2-8 hours is for both kinds of tests. Clerical hours at list of attachments includes test data clerical hours. See prior text for a full discussion.

4. Delay Cost for the FINAL Form

Delay costs are the same for this option as for other options. As before they range from $1,054,500 to $1,843,460.

5. Costs of Restrictive Actions for the FINAL Form

Changes to the EPA82 proposed form were made solely to insure that the FINAL required form would result in the risk reductions consistent with those achieved using the EPA79 form. Obviously, achieving these risk reductions requires that restrictive action costs be incurred. The number of restrictive actions should not differ from those made with the EPA79 form. Therefore, costs of restrictive actions are the same as they were for the EPA79 form -- $2,605,300-$4,038,200.

6. Summary of Costs for the FINAL Form

Exhibit VIII-2 provides the cost estimates for the proposed FINAL Form.

EXHIBIT VIII-2

TOTAL ANNUAL INDUSTRY COSTS OF THE FINAL FORM
(Thousands of 1981 Dollars)

Cost of Forms	$1,170 - $6,750
Confidentiality	$330 - $330
Delay	$1,055 - $1,843
Restrictive Actions	$2,605 - $4,038
Total Costs	$5,160 - $12,961

C. SMALL BUSINESS IMPACT

In Chapter VI the effects of the PMN program generally and the EPA82 form specifically on small business were addressed. In this section the impact of the FINAL form on small business is measured using the same parameters used there. In Chapter VI we estimated the costs that small business would bear, and the effect of those costs on profits and sales of small business. Then we compared the per-PMN costs with the expected present value of profits from new chemicals introduced by small business. For comprehensiveness small business was defined two ways: less than $30 million in annual sales and less than $100 million in annual sales.

1. Estimate of FINAL Form Impact on Small Business

From Chapter VI approximately 6.7 percent of the PMNs are submitted by companies with sales of less than $30 million; approximately 12.6 percent of PMNs are submitted by companies with sales of less than $100 million. Thus, small companies on average can be expected to absorb these percentages of the total industry costs of the program. From Exhibit VIII-2, the total industry program costs using the FINAL form are $5.2 to $13.0 million annually. Assuming per-PMN costs are constant across all firm sizes, firms with less than $30 million in annual sales then must absorb costs in the range of $348,000 to $871,000 (6.7% of the total cost). Firms with less than $100 million in annual sales must absorb $655,000 to $1,638,000 (12.6% of the total industry costs).

The effect of these costs on these firms is measured by comparing the section 5 costs to the total sales volume and estimated annual profits of the smaller companies. From Chapter VI, we know that the total sales of companies submitting PMNs with annual sales less than $30 million each year is $317 million. Thus the cost ($348,000 to $871,000) is only .1 percent to .27 percent of total sales. Assuming industry pre-tax profit margins of 12 percent, the cost would represent 0.9 percent to 2.3 percent of profits.

When considered in the context of the larger definition for small firms (annual sales less than $100 million), the impacts are even less. The adjusted total annual sales of these companies is approximately $2 billion. The $655,000 to $1,440,638 total cost is between .03 percent and .08 percent of sales, and is 0.3 percent to 0.7 percent of profits of these firms, assuming a pre-tax profit margin on sales of 12 percent.

Exhibit VIII-3 summarizes these findings.

EXHIBIT VIII-3

IMPACT OF TOTAL FINAL FORM COST TO SMALL BUSINESS MEASURED AS A PERCENTAGE OF SALES AND PROFITS

Small Business Definition	Sales	Profits
Annual Sales § $30 million*	.10 - .27%	0.9 - 2.3%
Annual Sales § $100 million**	.03 - .08%	0.3 - 0.7%

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*Average sales of firms in this category are about $12 million annually.
**Average sales of firms in this category are about $36.6 million annually.

2. Estimate of Impact Per New Chemical

In Chapter VI we estimated the present value of the profit stream from a "typical" small manufacturer's new chemical to be between $38,000 and $767,000 (see Exhibit VI-7) for less than $30 million companies and $144,000 to $2,868,000 for less than $100 million companies. We compared the cost estimate per PMN with the present value of per-chemical profits for three cases. The "best" case for both types of small firms is the lowest possible PMN cost ($5,800) along with the highest possible present value of profits ($767,000 for firms below $30 million). Similarly, the worst case is the highest possible PMN cost and the lowest possible present value for per-chemical profits. Finally, the average case combines the mid-range of both the PMN cost per-chemical ($10,100) and the present value of profits per chemical for a 30 percent pre-tax profit margin.

Exhibit VIII-4 illustrates the best, average, and worst cases that might occur from these possibilities.

EXHIBIT VIII-4

PMN COST AS A PERCENT OF PRESENT VALUE OF EXPECTED PROFITS

Type of Firm	Best Case	Average Case	Worst Case
Sales Below $30 Million	0.8%	4%	38%
Sales Below $100 Million	0.2%	1%	10%

Based on this analysis, it appears that in a worst-case situation, small firms (especially those below $30 million in annual sales) could potentially be significantly affected by section 5. The respective percentages for the average-case situation are approximately 4 percent for firms below $30 million and 1 percent for those below $100 million. In the best situation, all small firms incur costs which are less than 1 percent of the present value of the profit stream.

D. BENEFITS FROM THE FINAL FORM

Based on a retrospective analysis of problem chemicals, the Agency determined that the FINAL form would result in increased health benefits compared to the EPA82 form. Exhibit VIII-5 compares the probabilities of regulatory activities being taken with the FINAL and EPA82 forms. The FINAL form is intended to give the same regulatory actions as the EPA79 form and for the problem chemicals examined the same outcome was generated for all but one

EXHIBIT VIII-5
PROBABILITIES OF REGULATORY ACTIONS USING EPA82 AND FINAL FORMS AS COMPARED TO EPA79 FORM

Case Number	Reason for Less Probability of Regulatory Action Being Taken with EPA82 Compared to EPA79 Form	FINAL Form As Compared to EPA79 Form
PMN A	Insufficient occupational exposure information.	Sufficient information for EPA to ask the necessary questions to regulate the substance.
PMN B	Lack of processor/consumer exposure information; lack of chemical identity information.	Improved exposure and chemical identity information.
PMN C	Identification of the existence of consumer exposure.	Form contains check box for consumer use.
PMN D	Same action would have occurred (identity of impurities and MSDS submission required).	Same action would have occurred (identity of impurities and MSDS submission required).
PMN E	Same action would have occurred.	Same action would have occurred.

chemical. One chemical (PMN J) resulted in a slightly different outcome using the FINAL form and is discussed below.

The problem PMN, whose outcome changes with the FINAL form, was PMN J (see Appendix F). This PMN, submitted on the EPA79 form, contained a very detailed assessment of commercial use, the ultimate use. Since commercial use was the major concern of the Agency, and the PMN had a low SAT rating, unless detailed information was available on commercial use it is unlikely that regulatory action would be taken. The FINAL form does not require detailed information on use and therefore it is unlikely that this form would result in the same regulatory action as EPA79. As a result the FINAL form would result in approximately a 15% chance of not getting voluntary action (change in TSDS) to regulate the substance.

E. CONCLUSIONS

Exhibit VIII-6 compares the FINAL form costs to the cost of the other forms. As the exhibit shows, the FINAL form represents a 25%-37% reduction in cost relative to the EPA79 form.

EXHIBIT VIII-6

COMPARISON OF ANNUAL INDUSTRY COSTS
(Millions of 1981 Dollars)

	Total Annual Cost	Savings Over EPA79 Form
EPA79 Form	\$6.9 - \$20.6	— —
CMA Proposal	\$4.8 - \$11.5	30% - 44%
EPA82 Form	\$4.8 - \$11.4	30% - 45%
FINAL Form	\$5.2 - \$13.0	25% - 37%

As mentioned at the outset of this chapter, the FINAL form represents the culmination of years of analysis, debate, and rulemaking. Activities during the past few months have resulted in the development of much useful information that allowed the Agency to make refinements in the form that both reduced its cost and ensured adequate protection against unreasonable risks. Because of the intensity and duration of the analysis, it seems reasonable to believe that the FINAL form represents the option that provides the best ratio of benefits to costs. That is, the Agency believes that by promulgating this FINAL form it will achieve all of the benefits that it has achieved over the past three and half years while reducing the industry burden. When the proposed exemption rules are implemented, this burden will decrease even further. But, of course, the best measure of the success of this program in terms of reducing burden on industry will be the number of PMNs and exemption notices received by the Agency in the future. If the number of PMNs and exemption notices increase after these rules are promulgated, then the net benefit of this regulatory option will be demonstrated.

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APPENDIX A

UNIT COSTS OF LABOR

A. COST OF REQUIRED LABOR

Labor rates are important to the form cost analysis because they can be multiplied by hour estimates to derive the cost of submission. As developed below, these labor rates (in December 1981) were \$17/hour for clerical personnel, \$43/hour for technical personnel, and \$67/hour for managerial personnel. These rates are substantially higher than the rates used by ADL in 1978 (\$10/hour for clerical, \$25/hour for technical, and \$50/hour for managerial).

The subsequent paragraphs explain how these 1981 labor rates were derived and the methodology used for projecting 1978 rates. First data sources are reviewed, then estimates of clerical, technical, and managerial hourly costs in 1978 and 1981 are presented. These estimates are compared to Arthur D. Little, Incorporated (ADL) 1978 estimates and 1978 ADL estimates inflated to December 1981 using the GNP deflator.

ADL's 1978 labor rates for managerial and clerical personnel are very close to the corresponding labor rates that could have been developed using our methodology. However, ADL's technical rate was 10 percent to 34 percent too low.

B. SOURCES OF DATA

ICF updated the labor rates ADL used in its cost work because: 1) it has been over three years since publication of the first ADL report (December 1978); 2) inflation has been relatively high during this period;[39] and 3) ADL's technical rate was underestimated.

To update the labor costs, ICF intended to duplicate ADL's estimates using their methodology with more recent data. ADL's original cost estimates could not be replicated, however, because ADL's work provided no explanation of the analytical techniques used. Their report states:

> The staff time and costs required to complete each major section of the Notice Form were estimated by professionals familiar with the relevant areas. (ADL 1979 p19)

At the time the ADL report was being prepared, (September-October 1978), two sources of chemical industry data were available that could have been utilized to derive labor costs for each category. The first is the Labor Department's annual pay survey.(USDOL 1978) The second is the National Science Foundation's studies of the cost to support a Ph.D.-level researcher. (NSF 1981a, NSF 1978a, NSF 1978b).

In March of each year, the Department of Labor, Bureau of Labor Statistics (BLS) takes a national survey of selected professional, administrative, technical, and clerical occupations in private industry. This large scale survey examines annual salaries in several industrial classifications (chemist, engineer, etc.) and by job seniority category to determine what the comparable pay for U.S. government civilian employees should be. In 1977, the nationwide sample for the manufacturing sector was comprised of 1,799 establishments with 1,456,667 professional, administrative, supervisory, and clerical workers. Technical personnel were excluded. The minimum size of the chemical establishment surveyed employed 100 or more persons.

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[39] Between the second quarter of 1978 and the fourth quarter of 1981, the GNP price inflator increased by 34.6 percent. (USDOC 1982A, USDOC 1982B)

The National Science Foundation maintains statistical series about research and development that can be used to calculate the cost to maintain a Ph.D.-level researcher. These series are entitled: U.S. Scientists and Engineers and Research and Development in Industry. By dividing the annual research and development expenditure for the chemical industry by the number of scientists and engineers employed for R&D in the industry, a total cost per R&D professional can be estimated. Because research and development funds include wages and salaries, materials and supplies consumed, property and other taxes, maintenance and repairs, depreciation, and an appropriate share of overhead, we concluded that values computed from this data represent a maximum cost per technical person hour.

C. CALCULATION OF ICF ESTIMATES OF MANAGERIAL AND CLERICAL RATES

To calculate a labor cost for managerial and clerical personnel, the BLS mean annual salaries for the appropriate occupational category were adjusted to account for the additional costs of corporate overhead expenses, general and administrative expenses, and fringe benefits. Discussions with chemical companies whose sizes range from medium ($50 million in sales) to large ($500 million in sales) indicated that corporate overhead usually is 15 to 25 percent of direct labor costs; fringe benefits are 35 to 45 percent of direct labor costs; and general and administrative expenses are 50 to 60 percent of direct labor costs. In total, the additional corporate costs were estimated to range from 95 to 130 percent (approximately 110 percent on average) of direct labor costs.

As a cross-check on these overhead rates, CMA's 1981 survey results (CMA 1981c) were studied. Eleven firms provided salary rates and provided overhead rates that varied from 16% to 100%. Eighteen firms provided labor rates that included both salaries and overhead. The two samples, though not purely comparable, can be compared to arrive at estimates of the "typical" overhead in the surveyed chemical companies. Exhibit A-1 shows the comparison.

As the exhibit shows, RRS's survey results are very close to those determined here.

EXHIBIT A-1

RRS SURVEY RESULTS: CHEMICAL FIRM OVERHEAD a/
(1980 Dollars)

	Salary Rates (dollars/hr)	Full Rates (dollars/hr)	Full Rate/ Salary Rate	Overhead
Secretarial	6.80	17.26	2.5	150%
Technical	16.08	36.96	2.3	130%
Managerial	20.77	48.19	2.3	130%
Legal	50.49	62.47	1.2	20%
Unweighted Average	23.54	41.22	1.8	80%
Weighted by expected hours per category a/	17.15	36.60	2.1	110%

Source: CMA 1981, p A-8

a/ RRS did not report expected labor hours. Weights used here reflect mid-point hours estimated for the EPA79 form by ADL.

To arrive at a total annual cost, 110 percent of annual salary was added to the salary to reflect overhead costs. These costs were further adjusted for inflation using the GNP deflator to move annual March data forward to October 1978 and December 1981. In 1978 the appropriate factor was 1.046 and in 1981 the factor was 1.064.

To arrive at cost/hour, the annual salary was divided by the 2080 hours in a year. The aggregate calculation is illustrated in the equation below:

$$\text{Hourly Labor Rate} = \frac{[\text{annual salary} + 1.10 \times \text{annual salary}] \times \text{GNP inflator factor}}{2{,}080}$$

To estimate managerial cost, the chemist managerial level that would ordinarily review reports and documents being released by the firm was selected. This level, Chemist VIII,[40] which corresponds to a GS-15 level federal position, includes responsibilities for several subordinate supervisors or team leaders some of whose positions are comparable (USDOL 1977, p.51).

Clerical rates were also developed from the BLS reports. A mid-level clerical secretary category was selected, corresponding to a senior stenographer or upper GS-4 level secretary. This individual would take varied technical or specialized vocabulary dictation, or would be a secretary to an executive or managerial person (USDOL 1977, P.59).

To check for data bias that might have occurred because the reporting firms were generally large, a comparison was made between the median managerial salary data for the entire United States and the salary of persons in firms of more than 2,500 employees. The respective difference was negative 0.3 percent in 1978. Even though the BLS does not sample establishments with less than 100 people, the small wage difference between all firms and large firms indicates that including smaller firms would probably not appreciably change the national average direct labor costs.

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[40] Chemist Level VIII data was not reported in 1981 because the sample size is too small. Therefore, ICF assumed that these managers received on average the same increase over reported 1979 salaries as all other chemists--27.14 percent.(USDOL 1981)

1. 1978 Rates

Exhibit A-2 illustrates the hourly labor cost, additional corporate cost factor, inflation factor for the period from the first quarter 1978 to the second quarter 1978, and the resultant ICF estimates of total labor cost for managerial and clerical personnel. The ADL estimates are included for comparison purposes.

EXHIBIT A-2

SUMMARY OF ICF LABOR COST ESTIMATES
FOR MANAGERIAL AND CLERICAL CATEGORIES
(1978 Dollars)

Category	Average Direct Hourly Cost x	Total Additional Cost Factor x	GNP Inflator =	Adjusted Full Hourly Cost	ADL Cost
Managerial	$22.67	2.1	1.045 a/	$49.75	$50.00
Clerical	$ 5.29	2.1	1.045	$11.61	$10.00

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a/ First quarter to second quarter 1978.

To insure a proper perspective, ICF examined the full range of costs possible for the managerial category. Using the endpoint estimates for the additional overhead costs (95 to 130 percent), a range of total managerial cost of $46.20/hour to $55.67/hour was calculated. This outcome was very close to the ADL estimate.

2. 1981 Rates

Exhibit A-3 illustrates the calculation of the December 1981 managerial and clerical labor cost per hour, using March 1981 BLS survey data. The full range of ICF's managerial cost estimate, using the same endpoint estimates for the additional overhead costs as in the previous paragraph, was $62.10/hour to $74.84/hour.

EXHIBIT A-3

SUMMARY OF ICF LABOR COST ESTIMATES FOR MANAGERIAL AND ADMINISTRATIVE CATEGORIES
(1981 Dollars)

Category	Average Direct Hourly Cost	x	Total Overhead Cost Factor	x	GNP Inflator	=	Adjusted Full Hourly Cost	ADL 1978 cost Adjusted for Inflation
Managerial	$29.93		2.1		1.064 a/		$66.88	$66.07
Clerical	$ 7.56		2.1		1.064		$16.89	$13.21

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a/ First quarter 1981 to fourth quarter, 1981

D. CALCULATION OF ICF ESTIMATES FOR TECHNICAL RATES

1. 1981 Rates

Technical labor costs are not directly available from the BLS series. However, as mentioned above, the National Science Foundation annually collects and publishes data which can be used to derive the costs to support a Ph.D.-level researcher. The most recent data, originating from the National Science Foundation, appear annually in Chemical and Engineering News. These data include national averages for the total company cost (in constant 1972 dollars) to support a Ph.D.-level researcher in the chemical and allied products industry for one year in the years 1969 through 1979. To project a 1981 cost, a trend-line analysis using least-squares regression was performed. As shown in Exhibit A-4, this analysis yielded a cost of $50,400 per year measured in 1972 dollars.

EXHIBIT A-4

COSTS OF AN INDUSTRY R&D SCIENTIST OR ENGINEER IN THE CHEMICAL INDUSTRY
(Thousands of 1972 Dollars)

	Reported Cost	Trend Cost	Percent Deviation
1969	47.7	46.7	-2.1
1970	46.8	47.0	0.4
1971	45.5	47.3	4.0
1972	47.1	47.6	1.1
1973	48.3	47.9	-0.8
1974	49.0	48.2	-1.6
1975	48.5	48.5	0.0
1976	50.3	48.8	-3.0
1977	49.4	49.1	-0.6
1978	49.2	49.5	0.6
1979	48.8	49.8	2.0
1980(p)	--	50.1	--
1981(p)	--	50.4	--

(p)--projected

Source: ICF estimates and Chem Eng News 1981, 59(30):28

After adjusting for inflation using the GNP inflator, a mid-1981 annual cost of $97,564 was calculated in current dollars. The hourly labor rate was calculated by dividing $97,564 by the standard 2,080-hour work year. This calculation yielded a total hourly cost of $46.91 in mid-1981. Inflating this figure by 3.4 percent to account for changes in the price level between the second quarter and the fourth quarter resulted in a technical cost of $48.49 per hour.

2. 1978 Rates

Using only data available in late 1978 (1969 through 1975) and the same methodology, the 1978 technical labor cost would have been $49,614 in 1972 dollars. Using the GNP deflator, the mid-1978 cost was estimated to be $74,445, or $35.79/hour. This cost is significantly higher than the original

ADL estimate of $25.00. The ICF estimate is supported by at least one major chemical company, Nalco. Nalco presented a cost analysis and quoted a technical labor cost of $35.00/hour in its public comments on the ADL cost analysis in 1979 (Nalco Chem Co 1979).

As a check on ADL's technical estimate, ICF also considered the cost of the average Ph.D. chemist in private industry, as reported by the American Chemical Society based on a March 1981 survey. According to a Chemical and Engineering News report based on this data, the median annual salary in March 1981 of Ph.D. chemists was $39,000. (Chem Eng News, 1981 59(42)57). This figure translates into a cost per hour of $41.90, which is considerably more than an inflation-adjusted ADL estimate of $33.03.

As another check, we examined the median annual salary reported to the American Institute of Chemical Engineers by its members. This amount was $34,000 in March 1981 and, after adding overhead costs, yielded a cost per hour of slightly more than $36.52 in December 1981 (AICHE 1981, p.6). Even this "average technical person" would cost 10.6 percent more than the inflation-adjusted ADL estimate.

Therefore, it is clear that the ADL technical estimate was too low, and the cost per R&D scientist was the best cost per hour estimate to use for technical personnel.

E. CONCLUSION

Exhibit A-5 contrasts estimated December 1981 labor costs for each labor category with ADL estimates after inflating the ADL October 1978 values by the GNP deflator. The table shows that, on the basis of publicly available wage and price data, the ADL labor rates were reasonable for managerial and clerical personnel but were underestimated for the cost of technical personnel.

EXHIBIT A-5

COMPARISON OF HOURLY LABOR COSTS USING DIFFERENT METHODOLOGIES AND DATA SOURCES

Source	Fall 1978 Labor Costs	Labor Category	December 1981 Labor Costs
ADL:	$50	Managerial	$66
	$25	Technical	$34
	$10	Clerical	413
ICF:	$50	Managerial	$67
	$27-$38	Technical	$37-$48
	$11	Clerical	$17

The cost of reporting form options will be evaluated using December 1981 labor rates derived from publicly available data. These rates are shown in Exhibit A-6.

EXHIBIT A-6

CHEMICAL INDUSTRY LABOR RATES
(December 1981 Dollars)

Labor Category	Hourly Rate
Managerial	$67.00
Technical	$43.00
Clerical	$17.00

The estimates and costs per labor hour developed in this appendix are used in Chapter IV, Section B to estimate the form filing costs under each of the reporting and exemption options. In chapter IV, Section B the hour input estimates are developed.

APPENDIX B

DERIVATION OF FORMULA FOR DETERMINING PRESENT VALUE OF PROFITS DELAYED

Assume that P_i $(i=1,n)$ represents the real profits associated with the average new chemical

	1	2	3	1+t	2+t	3+t	n	n+t
Expected profit stream	P_1	P_2	P_3				P_n	
Expected profit stream (lagged t months)				P_1	P_2	P_3		P_n

Delay cost = (PV of profit flows with no delay) - (PV of profit flows with delay).

Let r = real (monthly) discount rate.

$$\text{Delay cost} = \sum_{i=1}^{n}\left[\frac{P_i}{(1+r)^i}\right] - \sum_{i=1}^{n}\left[\frac{P_i}{(1+r)^{i+t}}\right] = \sum_{i=1}^{n}\left[\frac{P_i}{(1+r)^i} - \frac{P_i}{(1+r)^{i+t}}\right]$$

$$= \sum_{i=1}^{n}\left[\frac{P_i\,[[1+r]^t - 1]}{(1+r)^{i+t}}\right] = \frac{(1+r)^t - 1}{(1+r)^t} \bullet \sum_{i=1}^{n}\left[\frac{P_i}{(1+r)^i}\right]$$

$$= 1 - \frac{1}{(1+r)^t} \bullet \text{PV of expected profit stream with no delay}$$

APPENDIX C

DESCRIPTION OF REVIEW PROCEDURE

Upon receipt of a premanufacture notice, EPA staff stamp the time of receipt and log it in to signal commencement of the 90 day review period. Then EPA staff conduct an administrative review. This review includes:

- a check to determine that the substance is not already on the TSCA chemical Inventory and that a notice is in fact required;
- composition of a letter to send the submitter acknowledging receipt of the notice;
- labeling and blacking-out for public file purposes any information which is claimed confidential and for which substantiation has been submitted with the notice;
- checking the notice for compliance with the requirements of TSCA; and
- preparation of a summary of the notice to be published in the Federal Register as required by section 5(d)(2) of TSCA.

A public file is then established which includes public inquiries and all non-confidential information regarding the notice. The staff that conducts the administrative review also tracks the notice through the subsequent review processes.

Following the administrative review, EPA chemists conduct a preliminary review of the notice. During this preliminary review, all chemicals listed in the notice are identified by name, function, and structure; any technical information is validated. The chemists outline the synthetic route that will be used to manufacture the substance and list the physical and chemical properties of the substance. These properties include the state of matter, molecular weight assessments of polymers, and any instabilities of the PMN substance.

A team of scientists then reviews the potential health and environmental effects of the chemical substance. This Structure Activity Team (SAT) identifies the toxicologically significant portions of the molecule to assist in the identification of structural analogs. This team assigns a number representing a level of concern for the potential health and ecological hazards posed by the chemical substance. These indicators of concern drive much of the later review. Those substances that receive low SAT scores for both health and ecological concern generally require little further analysis.

Following the SAT review, an interdisciplinary team reviews the chemical substance and other relevant material assessing the exposure and hazard information in the notice and pertinent literature. The purpose of this review is to identify substances for detailed review, for follow-up or referral actions, or whether substances should be dropped from further active consideration. As necessary, EPA staff conduct literature searches for information on structurally related analogs and consider whether the substance has potential for other uses in addition to the ones indicated in the notice.

After the interdisciplinary team has completed its assessments, a summary of the case and findings are put together along with staff recommendations for the ultimate disposition of the case. The case is reviewed by OTS management and is disposed of in one of the following ways:

1) Drop--EPA has reviewed the PMN, and intends not to take any further action at this time;

2) Drop/Follow-up--EPA will not take action during the notification period, but the Agency may subsequently consider whether to require follow-up reporting; e.g., a Significant New Use Rule or section 8(a) rule for another use (or higher production volume);

3) Detailed Review--implies some concern by the Agency for the health or ecological effects resulting from use of the PMN substance, and that further analysis by the Agency is needed before a decision is made.

If further analysis is necessary, an interdisciplinary team does an indepth study of the case. After completing these analyses, EPA staff recommends either to end active consideration of the notice or to continue the review and contemplate Agency action. Occasionally, EPA takes a section 5 control action.

When a chemical is not subject to section 5 control action, EPA expends no further resources on it, except to send a letter to submitters indicating that the Agency has stopped its review of the chemical. Submitters, of course, must wait until the review period expires before manufacturing or importing the chemical substance.

This set of activities constitute the normal PMN review process. As described above it can be broken down to four separate activities:

- administrative review (document control) and in-house tracking
- initial review
- detailed review
- section 5 control action.

APPENDIX D

COMPARISON OF FOUR REPORTING OPTIONS

EPA79 FORM	CMA79 FORM	FINAL FORM	EPA82 FORM
I. General Information			
A. Submitter's Identity		adds type of notice (import or manufacture)	
1. person filing notice	no change	no change	no change
2. technical contact	no change	no change	no change
3. parent company	deleted	deleted	deleted
4. manufacture commencement date	deleted	deleted	deleted
5. prenotice communication information	deleted	adds TME and bonafide request questions	deleted; adds TME and bona-fide request questions
B. Chemical Identity			
1. Class 1 chemical substance			
a. CAS Registry No.	no change	no change	no change
b. specific chemical name	no change	no change	no change
c. molecular formula	no change	no change	no change
d. synonyms	no change	no change	no change
e. trademarks	no change	no change	no change
f. structural design	no change	no change	no change
2. Class 2 chemical substance			
a. CAS Registery No.	no change	no change	no change
b. specific chemical name	no change	no change	no change
c. synonyms	no change	no change	no change
d. trademarks	no change	no change	no change
e. immediate precursors & reactants, nature of reaction, structural diagram	no change	no change	no change

COMPARISON OF FOUR REPORTING OPTIONS
(cont'd)

EPA79 FORM	CMA79 FORM	FINAL FORM	EPA82 FORM
I. General Information (cont'd)			
3. Polymers		**	*
a. monomers and CAS Register No.	no change	no change	no change
b. minimum average molecular weight	deleted	no change	no change
4. Impurities			
a. CAS Registry No.	no change	no change	no change
b. maximum percent present	no change	no change	no change
c. concentration controlled	deleted	no change	deleted
C. Generic Names		***	
(completed if specific chemical identity is claimed confidential)	no change	no change	no change
D. Production and Marketing Data			
1. Annual Production (Minimum & Maximum)			
a. 1st year	no change	1st 12 months plus max. of any 12 months production	of 1st 3 yrs., max of any 12 mos. production
b. 2nd year	no change		
c. 3rd year	no change		

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*Requires the following additional information beyond EPA79 requirements: (1) method used to derive molecular weight; (2) structural diagram; and (3) additional information on low molecular weight species (weight percent less than 1,000 and less than 2,000 "typical composition").

**Same as EPA82 except that additional information on low molecular weight species is for those with weight percent less than 500.

***Add Byproducts questions here. Questions about byproducts were included under site information on other forms.

COMPARISON OF FOUR REPORTING OPTIONS
(cont'd)

EPA79 FORM	CMA79 FORM	FINAL FORM	EPA82 FORM
2. Category of Use			
a. use categories	no change	no change	no change
i. production pct.	no change	no change*	no change
ii. site limited, industrial, commercial, consumer	deleted	no change	deleted
b. other categories explored	deleted	deleted	deleted
c. used to treat drinking water or used in products that come in contact with same	deleted	deleted	deleted
3. Has substance been manufactured before?	optional	deleted	deleted
4. Hazard warning (copy provided)	optional	no change	no change
5. No. of customers committed to purchase and pct. of production involved	deleted	deleted	no change
E. Transport			
1. DOT shipping name and hazard class	optional	deleted	deleted
2. mode(s) of transport	optional	deleted	deleted
F. Risk Assessment (evaluation of health/ environmental mental risk due to manufacture, processing, use, etc.)	optional	deleted	optional
G. Detection Methods (are analytical methods available to identify the substance in various media)	optional	deleted	deleted

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*Add formulation percent.

COMPARISON OF FOUR REPORTING OPTIONS
(cont'd)

EPA79 FORM	CMA79 FORM	FINAL FORM	EPA82 FORM
II. Human Exposure and Environmental Release			
A. Industrial sites controlled by submitter			
1. Process info.			
a. identity of site	no change	adds number of sites	deleted
b. site type	deleted	no change	no change
c. hours operated	optional	adds batch/day	no change
d. amt. manufactured, processed, used	optional	no change	deleted
2. Block diagram (identifies major operations and chemical conversions; indicates opened and closed points of material transfer andpoints of release to environment)	deleted	further simplified to identify only where NCS leave process	simplified no chemical reactions
3. Occupational exposure			
a. site identity	no change	deleted	deleted
b. exposure of site (routes, no. exposed, duration, concentration)	no change (duration, no. & route)	*	no change duration, no. & route
i. manufacture			
ii. processing			
iii. use			
iv. disposal			
c. description of operations where workers are directly exposed	deleted	deleted	deleted

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*Major revision. Submitter identifies worker activities. For each worker activity the physical form, maximum number exposed, and maximum duration are provided.

COMPARISON OF FOUR REPORTING OPTIONS
(cont'd)

EPA79 FORM	CMA79 FORM	FINAL FORM	EPA82 FORM
II. Human Exposure and Environmental Release (cont'd)			
d. physical states of substanceto which workers may be exposed	deleted	determined above	no change
e. list and give CAS No. of other substances (byproducts, etc.) to which workers may be exposed	no change	provided above	optional
4. Environmental Release/ Disposal			
a. site identity	no change	deleted	deleted
b. duration and amount of substance released			
i. air	optional	*	duration no change amount deleted
ii. land	optional		
iii. water	optional		
iv. effluent stream flow rate	optional		deleted
c. composition of release materials at each point of block diagram	deleted	*	optional
d. pollution control equipment and disposal operations used for releases	optional	*	no change
e. water discharge destination	optional	no change	no change
B. Industrial Sites Controlled by Others	(same as own	**	deleted

---

*Match of release points with II.A.2. Provide amount, media, and control technology for each release point.

**General description of exposure and release to be provided in narrative form.

COMPARISON OF FOUR REPORTING OPTIONS
(cont'd)

	EPA79 FORM	CMA79 FORM	FINAL FORM	EPA82 FORM
II.	Human Exposure and Environmental Release (cont'd)			
C.	Consumer and Commercial User Exposure		deleted	option of providing demographic data
1.	Exposure information:			
	a. whether consumer or commercial	optional		
	b. manufactured by submitter or others	optional		
	c. exposure routes	optional		
	d. maximum number exposed	optional		
	e. frequency of exposure	optional		
2.	Estimates of potential exposureby category (if any)	optional		
3.	For these products, explain aspects that will cause exposure to the new substance; for mixtures, give maximum percentage of weight by new substance	optional		
4.	By-products formed from each category of use	deleted	provided above	
III.	List of Attachments		*	
A.	Physical/Chemical Properties Data	deleted	deleted	deleted
B.	Health & Environmental Effects Data	no change	no change	no change

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*Submitter provided a table of contents for additional information such as test data, optional information, and confidentiality attachments.

COMPARISON OF FOUR REPORTING OPTIONS
(cont'd)

	EPA79 FORM	CMA79 FORM	FINAL FORM	EPA82 FORM
III.	List of Attachments (cont'd)			
C.	Notice Amendments	no change	no change	no change
D.	Confidentiality Attachments	no change		no change
E.	Voluntary Agreements	optional		no change
IV.	Federal Register Notice		deleted	deleted
A.	Chemical Identity	no change		
B.	Manufacturer Identity	deleted		
C.	Use Data	no change		
D.	Test Data	no change		

APPENDIX E

R&D SPENDING ON NEW CHEMICAL PRODUCTS

The purpose of this appendix is to estimate R&D spending on new products by the chemical industry before and after section 5 of TSCA went into effect. TSCA section 5 may have affected the pace of new product development in the chemical industry because section 5 regulates the introduction of new chemical substances and significant new uses of existing chemicals (although it is not yet clear how this latter authority will be used).

As discussed in Chapter V, by examining trends in R&D spending, this appendix lays the groundwork for estimating the producer surplus on new products developed by the chemical industry. To isolate potential regulatory effects on innovation, we distinguish expenditures for new product development from spending on productivity improvement and brand proliferation.

This appendix is organized as follows:

- Section A: discusses the data and methods used to develop the estimates of new product R&D spending.
- Section B: presents and discusses actual trends in total and new product R&D spending.
- Section C: breaks the series into two time frames: pre- and post-1979, compares the two periods to evaluate potential TSCA section 5 effects, and discusses possible transition phase distortion.

A DEFINITIONS, DATA, AND APPROACH

Information on R&D expenditures by industry is available from several sources. However, independent sources usually do not agree. In part, alternative estimates reflect the use of different definitions of key terms. We have specified a set of working definitions to avert confusion and facilitate comparison of data from different sources. After discussing these definitions, we outline the data sources and estimation methods.

1. Definitions

The most widely used information on total R&D expenditures is developed by the National Science Foundation (NSF). Because the NSF data are the basis of this analysis, we have adopted definitions generally consistent with those used by NSF [NSF 1981, pp. 79-88]. The relevant definitions are:

- The chemical industry includes all chemical and allied products firms classified as SIC 28 in the Standard Industrial Classification Manual. The three principal groupings within SIC 28 are: industrial chemicals (SIC 281-82, 286), drugs and medicines (SIC 283), and other chemicals (SIC 284-85, 287-89). Some firms not affected by TSCA are in this category. For example, SIC 28 includes pharmaceuticals, cosmetics and agricultural chemicals, all of which are potentially regulated by other legislation.[41] On the other hand, SIC 28 does not include certain types of firms (e.g., photographic chemicals and equipment) that may be affected by TSCA. Unfortunately, the SIC data do not permit disaggregating to correct fully these imprecisions.

- Research and development include basic and applied research in the sciences and engineering as well as the design and development of prototypes and processes. This definition excludes quality control, routine product testing, market research, sales promotion, sales service, and research in the social sciences or psychology.

- Expenditures for research and development are funds for operating expenses incurred in the conduct of research and development in a company's own laboratory or other company -owned or -operated facilities. These expenses include wages and salaries, materials and supplies, property and other taxes, maintenance and repairs, depreciation, and an appropriate share of overhead. Capital expenditures are excluded. Although total R&D expenditures include federal funds, for our purposes we will be looking only at company-financed expenditures.

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[41] The principal governing legislation for pharmaceuticals and cosmetics is the Federal Food, Drug, and Cosmetics Act (1962) and for pesticides, the Federal Insecticide, Fungicide and Rodenticide Act (as amended, 1978).

- Expenditures for new product R&D cover the cost of basic and applied R&D expenditures for the advancement of scientific knowledge and development of new products, as well as new technologies necessary to bring new products to market. Included are significant improvements and modifications of existing products. For example, in the chemical industry, new product R&D spending may include outlays on:

  - new chemical entities,
  - new formulations, containing new chemical entities, and
  - significant new applications of existing chemicals.

- Expenditures for process R&D include the cost of research oriented mainly toward improving the efficiency of manufacture for existing products.

- R&D expenditures for new brands include expenses for researching and developing a new brand of a product already in the market. New brands are not new products unless they comprise a new formulation or chemical ingredient.

2. Data Sources

The data used to estimate new product R&D expenditures are mainly from five sources. Four of the sources used here estimate R&D expenditures: the National Science Foundation, McGraw-Hill, a survey conducted by National Economic Research Associates for the Chemical Manufacturers Association, and the Pharmaceutical Manufacturers Association series. Each set of estimates is independent in that it uses a different survey instrument, sample, and time frame. Where surveys overlap, multiple sourcing enables crosschecking; and gaps and deficiencies in one source often can be offset by information collected by another source.

The fifth source of R&D information (a study by the Regulatory Research Service for the Chemical Specialties Manufacturers Association) focuses on the characteristics of actual R&D projects in a segment of the chemical industry. Although not directly translatable into dollars, nor representative of the entire industry, this detailed product information highlights some complex problems associated with distinguishing new product from other R&D expenditures. The data are used qualitatively to form our interpretation of R&D spending data.

The following sections discuss the data sources and problems in using each individually.

a. National Science Foundation Series (NSF 1981)

The National Science Foundation (NSF) compiles R&D expenditure data that is the most reliable available in the sense of being based on a representative sample.

The NSF data are derived from an annual survey of all manufacturing and some (research performing) service industries. On the basis of a representative sample (NSF 1981, pp. 3-7) composed of approximately 11,500 companies, NSF estimates R&D expenditures by funding source (company or government) and broad use (applied versus basic research). Because NSF also compiles industry sales data, trends in R&D expenditures can be assessed in the context of overall sales growth.

A particularly useful feature of the NSF data is that a consistent series is available from 1956. Unfortunately, the most recent data available are for 1979. Although NSF data do not illuminate post-TSCA effects, the NSF series does provide a good picture of the trend in total company-financed R&D expenditures.

Unfortunately, NSF historically has not distinguished process from product-oriented R&D. Some information is available, but only for 1979. That year is the first in which companies were asked to differentiate product from process R&D. Even so, companies were not asked to break product R&D spending into new product expenditures and spending on new brands of existing products. Fortunately, this weakness of the NSF data is addressed by other sources.

b. McGraw-Hill Series (McGraw-Hill 1981)

McGraw-Hill Publications also conducts an annual survey of R&D expenditures by industry. Like NSF, McGraw-Hill bases its estimates on a sizable sample (450) of firms in both manufacturing and service industries. Unlike NSF, the McGraw Hill sample is not truly representative; it is skewed toward larger companies. However, the firms in the McGraw-Hill survey account for a disproportionately large amount of investment -- approximately one-third of all industrial capital expenditures. Thus, the McGraw-Hill survey emphasizes the expenditure patterns of major spenders. Data on total capital spending and sales provide a frame of reference for assessing R&D trends.

McGraw-Hill's data cover largely the same time period as the NSF series. Consistent data are available from 1956. However, the McGraw-Hill data extend through 1981, with projections to 1984. Thus, McGraw-Hill provides a useful crosscheck to NSF over the 1956-1979 period and can be used to evaluate the period immediately following the date section 5 of TSCA became effective.

A particularly valuable aspect of the McGraw-Hill survey is the inclusion of a question on the breakdown of spending between product and process R&D.

As a result, we have information for selected years beginning in 1966 on the product-process delineation. This is important for evaluating the hypothesis that regulation of the substances may have encouraged a shift from product to process innovation. Additionally, the McGraw-Hill data distinguish spending on new product development from expenditures to modify existing products. This is a necessary step toward assessing potential effects of regulation on chemical innovation.

As a cross check, the product-process proportions shown for 1979 by McGraw-Hill are virtually the same as the percentages in the NSF breakdown. However, data collected by the National Economic Research Associates (NERA) do not agree as well.

c. National Economic Research Associates (NERA) Data (NERA 1981)

The National Economic Research Associates (NERA) performed a pilot study (released in 1981) of TSCA-related impacts for the Chemical Manufacturers Association (CMA). The objective of the study was to develop and test a methodology for assessing the costs of compliance with TSCA. In this connection, NERA surveyed 36 members of the Chemical Manufacturers Association on a range of questions including R&D expenditures in 1977 through 1979.

A primary weakness of the NERA data is that the sample was both small and unrepresentative, only CMA members were surveyed and only a portion of that membership chose to respond. The result is a rather small (36), self-selected sample, skewed toward large firms. For these reasons, the NERA data are suspect and are used only as cross references, not as primary sources.

An advantage of the NERA survey is that it gathered information on the spending breakdown between process and product and between new and existing products. While the NERA data appear to differ somewhat from the NSF and

McGraw-Hill findings, they may be useful for establishing a reasonable range for the proportion of R&D going to new products.

d. The Pharmaceutical Manufacturers Association Series (PMA)

The Pharmaceutical Manufacturers Association (PMA) has surveyed its membership annually since 1959. PMA represents 149 member firms that account for between 90 and 95 percent of U.S. ethical pharmaceuticals production. Because ethical pharmaceuticals account for most of R&D spending by the drugs and medicines category of SIC 28, the PMN survey are very similar to NSF's results for the drugs and medicines category.

The PMA collects data on sales and R&D expenditures by U.S. pharmaceutical manufacturers both in the U.S. and abroad. Domestic spending is identified separately. In addition, PMA requests a breakdown between new and existing products.

Unfortunately, the PMA data do not distinguish well how much of the R&D spent on new or existing products was for process improvement. However, PMA gives some information on the proportion of all R&D spent on "Process Development for Manufacturing and Quality Control" which can be used to estimate process R&D spending.

The PMA data will be used to separate drugs and medicines from the rest of SIC 28. This is important because drugs and medicines are not affected by section 5 of TSCA. Moreover, drugs and medicines, as a group, is one of the largest segments of SIC 28 in terms of R&D expenditures.

e. Chemical Specialties Manufacturers Association Data (Heiden and Pittaway 1982)

The Chemical Specialties Manufacturers Association (CSM) recently sponsored a study of TSCA's impact on chemical innovation. The study, performed by Heiden and Pittaway of the Regulatory Research Service, highlights some special problems with using R&D expenditure data.

The study was based on a survey of CSMA members who were potentially affected by TSCA.[42J] Among other things, this survey collected information on the characteristics of recent product innovations during the period 1976-1981. The CSMA survey describes whether product innovations by the sample firms were for existing or new products. For each category, the data show whether the innovation involved a new formulation, a new use of an existing chemical, or a new chemical substance. These data show that:

- spending on new product may be oriented toward development of new brands rather than discovery of new chemical entities and formulations;
- modification of existing products may produce new chemical entities and formulations; and
- from the standpoint of section 5 TSCA effects, expenditures on existing products may be as relevant as spending on totally new products.

In contrast to the other four data sources, CSMA does not give R&D expenditures for these new product innovations. Consequently, there is no way to relate directly the CSMA product information and other available R&D spending data. Even if the CSMA data could be translated into dollars, its usefulness would be limited because it is not representative of the whole chemical industry. The CSMA survey is based on 100 self-selected respondents

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[42J] CSMA sampled by mail 198 ingredient suppliers and product manufacturers. Sixty-nine of the firms (35%) responded. An additional 31 firms were surveyed by personal interview. The resulting sample of 100 firms is distributed like CSMA's membership in terms of type of manufacturing operation and sales volume. It is not necessarily representative of non members (15 percent of the chemical specialties industry are not CSM members) or of the chemical industry as a whole.

from only the specialties segment of the chemical industry. As a result, the CSMA information may be used qualitatively only to develop R&D spending data for the purpose of this analysis.

3. Estimation Approach

This appendix has two purposes: to construct a data series for R&D spending by the chemical industry for new product development and to identify whether major shifts in this series coincide with the effective date of section 5 of the Toxic Substances Control Act.

A major feature of this approach to estimating R&D expenditures is that it combines information from four independent sources. Consequently we had to establish working definitions that would ensure consistency. Despite our efforts, inconsistencies and gaps among the sources remain. Bridging these gaps required making key assumptions on the basis of incomplete information. To preclude any inference of unjustified precision, we present our findings in terms of relevant ranges rather than point estimates.

The approach for estimating new product R&D expenditures involves three major steps:

- estimating total company-financed R&D expenditures made by the chemical industry for several years prior to and following the effective date of section 5 of to TSCA;
- estimating a reasonable range for the proportion of total R&D denoted to new product innovation before and after TSCA;
- applying this proportion to the estimate of total R&D expenditures to derive the likely range of expenditure for new product R&D in selected years between 1966 and 1981.

Having constructed the new product R&D expenditures series, the next step is to assess whether TSCA section 5 coincided with any observable shifts in such spending.[43] To do this, we will:

- determine whether actual new product R&D expenditures after TSCA section 5 were in the range expected on the basis of pre-TSCA trends;
- discuss possible transition phase distortions.

B. ESTIMATES OF NEW PRODUCT R&D EXPENDITURES BY THE CHEMICAL INDUSTRY

As discussed in the previous section, information on R&D spending is available from several sources. However, no single source provides enough data to construct a series on chemical industry spending for new product R&D. The NSF series on total company R&D expenditures formed the basis of our estimates. R&D spending by the chemical industry includes expenditures by all of SIC 28. To arrive at new product R&D spending potentially subject to section 5 of TSCA, these data were adjusted using information from other sources as follows:

- The NSF data go only as far as 1979. To extend the series to 1981 (and project it to 1984), we applied the annual rates of increase in the McGraw-Hill series. Historically, the two series had shown almost identical annual rates of change.
- The extended series of expenditures was converted to constant (1981) dollars using the GNP deflator (the index used by NSF). NSF found no appreciable

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[43] We note that several factors other than TSCA could have contributed to shifts in the R&D series (e.g., the Occupational Safety and Health Act, actions of the Consumer Product Safety Commission, private court actions general economic conditions). Given the focus of this report, we use TSCA as short hand for all of these effects. As indicated in Chapter 2, later analyses may attempt to estimate the effects of TSCA's section 5 with greater precision.

difference between the GNP deflator and a special price index for academic R&D expenditures that NSF had constructed. (NSF 1972)

- Total R&D spending was then broken into three categories: process, new product, and existing product. The McGraw-Hill data were used for the disaggregation.
- Because drugs and medicines are not regulated by TSCA and because they represent a large portion of SIC 28 R&D spending, we tried to separate drugs and medicines from SIC 28. Information collected by PMA on R&D spending by the ethical pharmaceuticals industry was the basis for the breakdown. Unfortunately, the PMA data do not break out process spending very well. We had to make some assumptions about how process R&D was distributed between the new and existing product categories. Despite its deficiencies, the PMA data are the best available.
- Based on the characteristics of actual product innovations reported by CSMA, we established a range for new product R&D.
- Using 1979 as the breakpoint for the implementation of section 5 of TSCA, we estimated a Baseline Research and Development Expenditures (pre-1979 R&D expenditures) and a Post section 5 Research and Development Expenditures (R&D expenditures made from 1979 to 1981).

The following sections provide detail on these steps.

1. Trends in Total R&D Expenditures

As noted in the definition section, this analysis considers only the company-financed portion of R&D expenditures. Most data on R&D expenditures by industry combine company with government funds as long as the research is performed in a private company's facility.[44] Such data are useful for indicating the total level of R&D activity conducted by the private sector.

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[44] The NSF data exclude R&D subcontracted out, because of duplication problems.

However, for this analysis, company-financed spending is more relevant because R&D estimates will ultimately be used as a lower bound for producer surplus.

Fortunately, the NSF data distinguish company and government R&D expenditures. For years after 1979, when other sources must be used, the estimation of the company portion in the chemical industry is relatively simple. Unlike industries, such as aerospace, which rely heavily on government research funding, the chemical industry has historically financed its own R&D. In contrast to other industries, there has been no significant shifting over time of funding burden between government and companies. Approximately 90 percent of all R&D has consistently been company financed in the chemical industry. (NSF 1981)

2. R&D Expenditures in Current Dollars

Exhibit E-1 shows total company-financed R&D expenditures for the period 1957 to 1984.[45] The trend in the chemical industry is compared with all industries combined to provide a point of reference.

Spending in industrial chemicals through 1979 is also shown in Exhibit E-1.[46] Under the assumption that most industrial chemicals are subject to TSCA, industrial chemicals may be viewed as a sort of minimum bound for R&D spending potentially susceptible to section 5 of TSCA. Unfortunately, post-section 5 trends for industrial chemicals are not available. The only source of information on industrial chemicals R&D spending is NSF, which does

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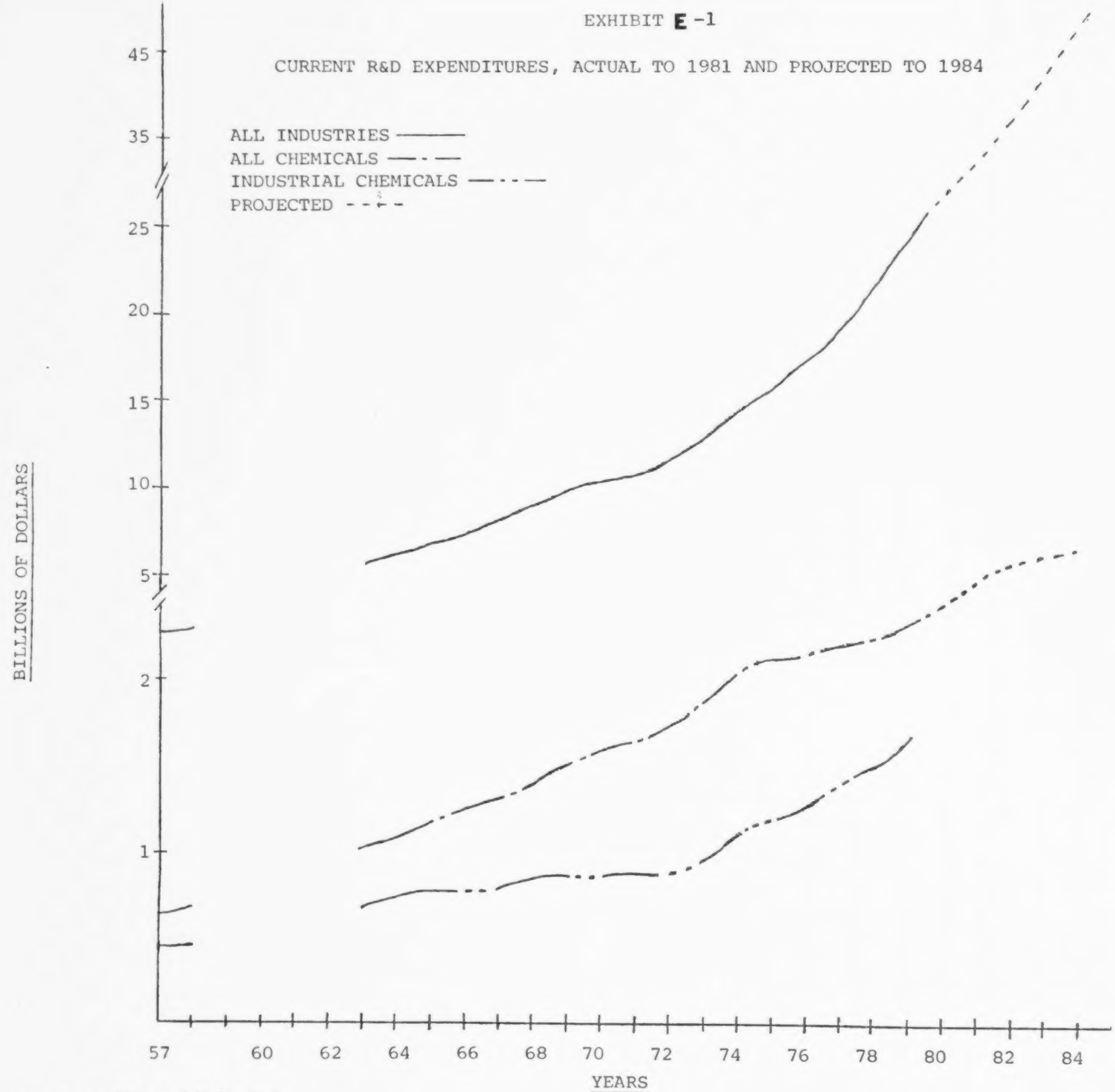
[45] Annual data were interpolated 1959 through 1962 and 1982 through 1983. See Appendix Exhibit C-1 for the data on which Exhibit E-1 is based.

[46] Industrial chemicals (SIC 281-82, 286) include establishments primarily engaged in manufacturing basic organic and inorganic chemical for industrial use as well as plastics, synthetic resins, synthetic rubbers, synthetic and other man-made fibers except glass.

EXHIBIT E-1

CURRENT R&D EXPENDITURES, ACTUAL TO 1981 AND PROJECTED TO 1984



Source: Appendix Exhibit C-1.

not go further than 1979. McGraw-Hill does not collect data from which post-1979 (post section 5) R&D spending on industrial chemicals can be inferred.

Several points emerge from the available data:

- Industry spends a large and consistently increasing amount of money on R&D. Between 1957 and 1981, R&D spending in current dollars increased from $3.4 billion to $34.4 billion. According to the McGraw-Hill survey of R&D plans, recent growth rates are expected to continue through 1984.
- The chemical industry is a major R&D spender. However, the chemical industry's rate of growth in R&D spending has been less than that of total industry for much of the time frame. Between 1957 and 1982, chemical R&D spending in current dollars increased from $0.6 billion to $5.0 billion.
- The chemical industry experienced a steady rate of growth in R&D spending except for the mid-70's. The steady trend is expected to continue through 1984 (according to McGraw-Hill).
- Industrial chemicals have strong growth in R&D spending through 1979. Industrial chemical R&D spending in current dollars grew from $0.4 billion to $1.7 billion between 1957 and 1979.

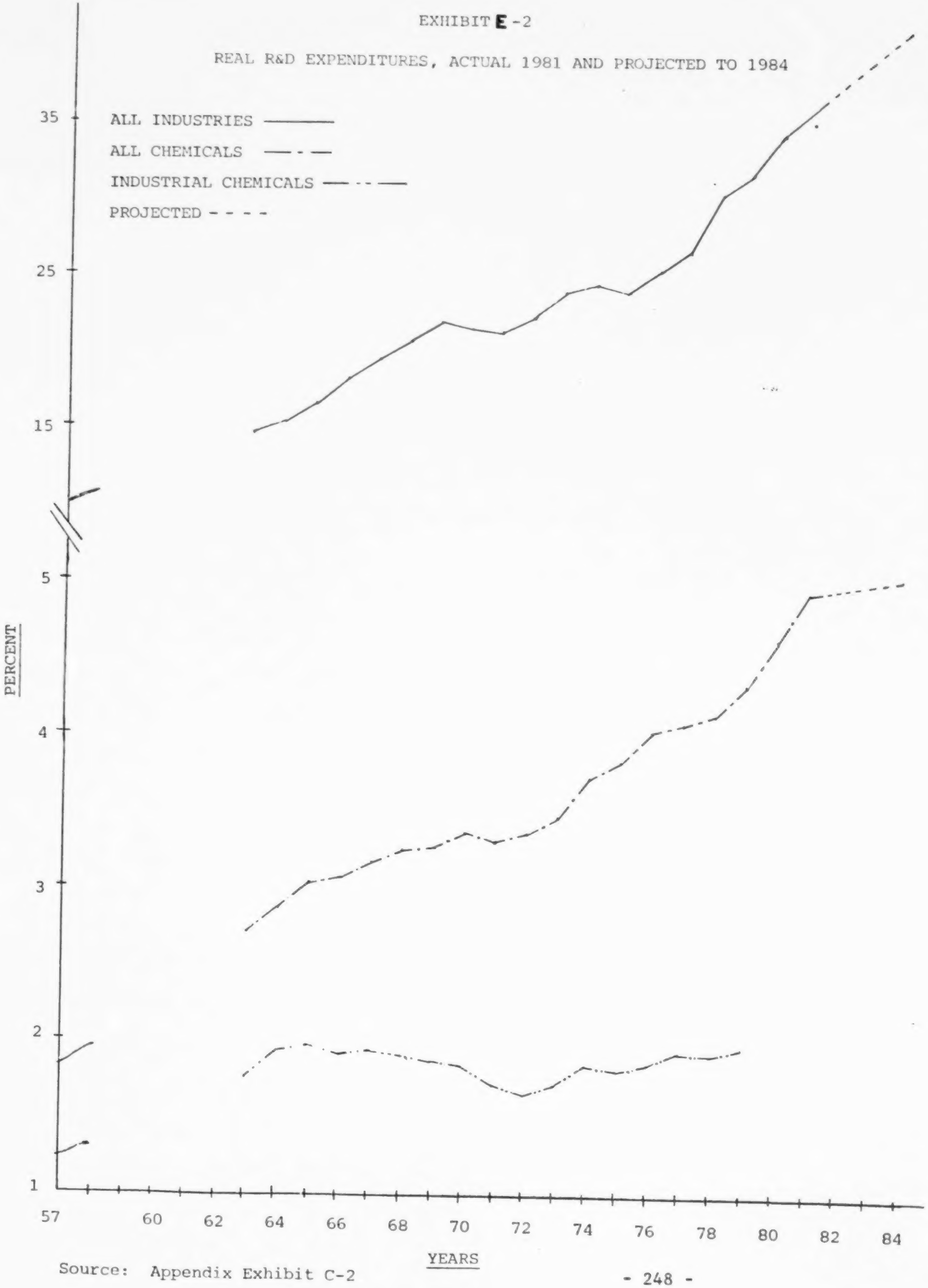
3. R&D Expenditures in Constant Dollars

Exhibit E-2 presents the same data translated to read 1981 dollars. Eliminating the distorting influence of inflation permits assessment of whether any significant change in R&D activity actually occurred.

- In the chemical industry, the high growth in R&D real dollar spending of the late 1950's and early 1960's tapered off significantly after 1965. From 1965 to 1974 R&D real spending by the chemical industry increased from $3.0 billion to $3.5 billion -- an average annual rate of 1.9 percent. R&D real spending actually declined in 1971. This pattern was generally reflected by all industry, implying the sensitivity of R&D spending to general economic conditions.

EXHIBIT E -2

REAL R&D EXPENDITURES, ACTUAL 1981 AND PROJECTED TO 1984



Source: Appendix Exhibit C-2

- R&D real spending, in chemicals as in all industry, surged after the mid 1970's (excepting the recession year 1975). R&D real spending on chemicals increased from $3.7 billion to $4.4 billion from 1973 to 1979. This amounts to an average annual real increase of 2.9 percent.

- Industrial chemical's real R&D spending declined from the mid 1960's to the mid 1970's. Between 1965 and 1973 R&D real spending declined from $2.0 billion to $1.7 billion or (2.0) percent annually. Although from 1973 to 1979 R&D real spending increased by 2.7 percent annually this only served to lessen previous losses. Only in 1979, did real R&D expenditures return to the 1965 level. Recent Chemical Week and CEN news article highlight the tremendous rebirth in R&D spending in the 1980's.

- These trends likely reflect a combination of factors. Possible contributors include economic conditions, renewed emphasis in the competitive need for R&D, tax law changes, or (particularly in chemicals) increased need to achieve efficiency in the use of oil after 1973. To the extent that efficiency improvement is a factor, one might expect to see a greater emphasis on process oriented R&D.

Fluctuations in R&D spending may reflect either changes in the amount of discretionary funds available to corporations or shifts in the allocation of available funds among competing uses. To get at this question we have examined various industrial indicators. Exhibit E-3 relates current R&D expenditures to current sales as a proxy for industry performance. Exhibit E-4 shows how current R&D expenditures compare to other current capital investments (mainly plant and equipment.)[47]

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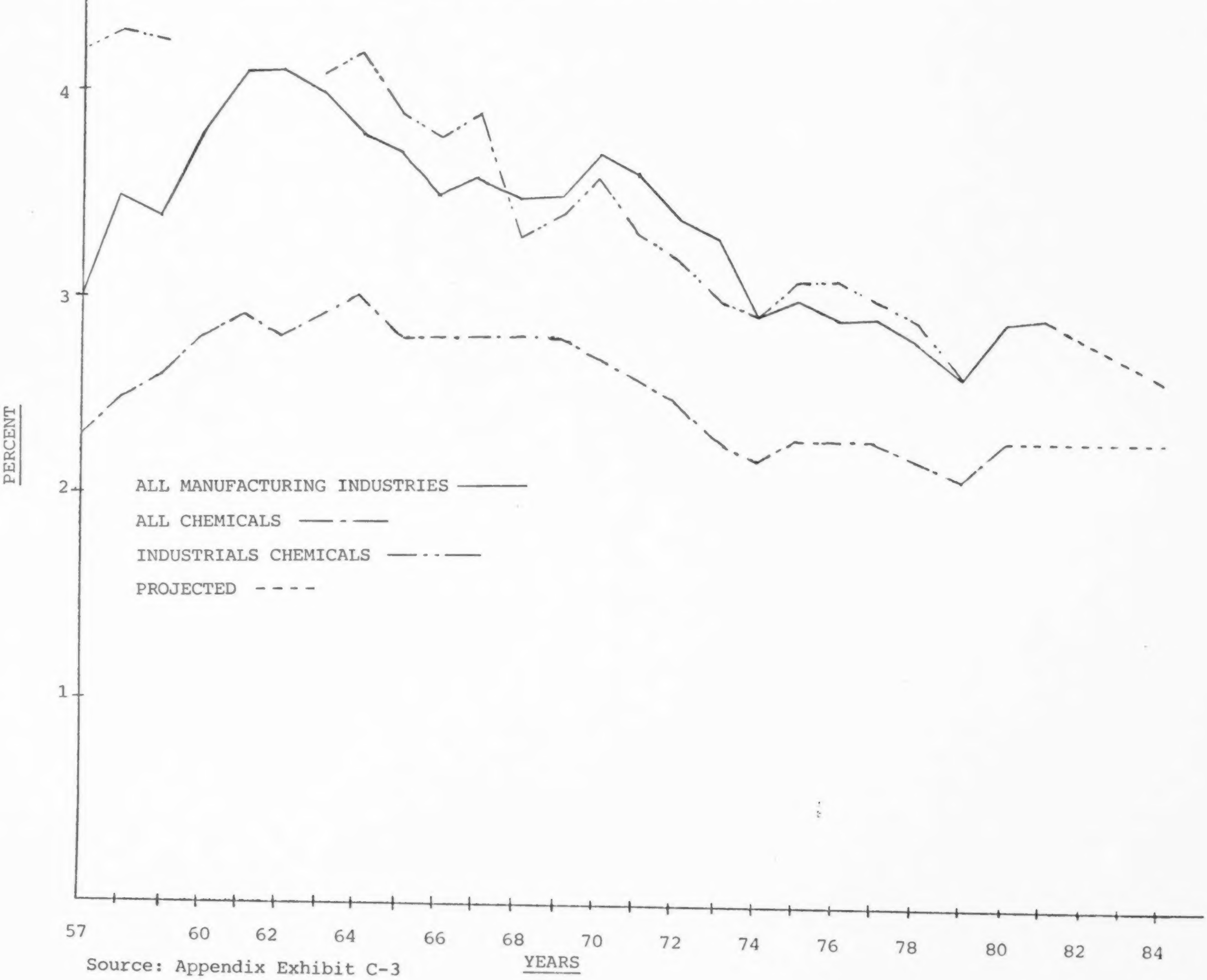
[47] These categories are mutually exclusive, R&D expenditures exclude capital investments.

EXHIBIT E-3

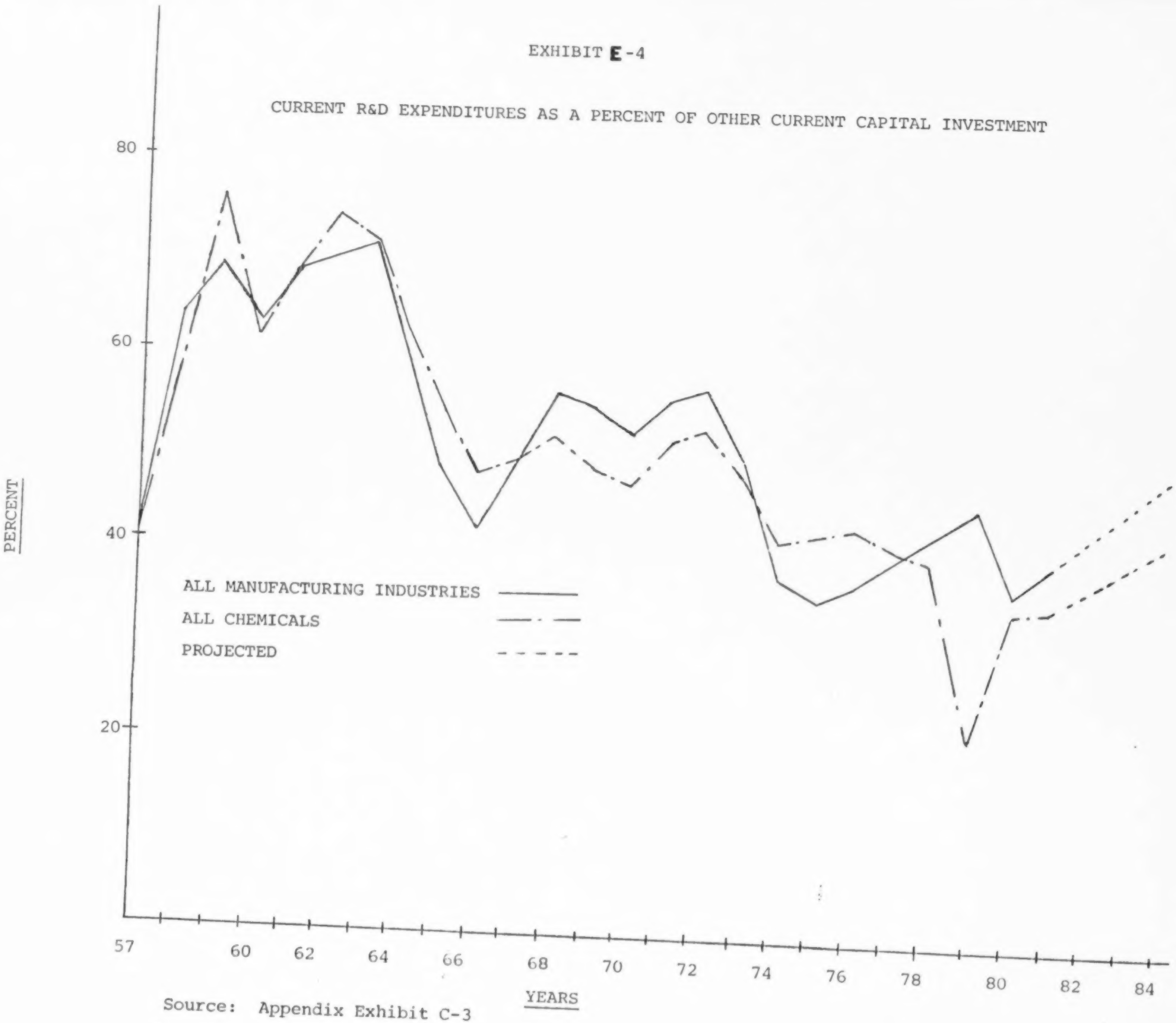
CURRENT R&D EXPENDITURES AS A PERCENT OF CURRENT SALES



Source: Appendix Exhibit C-3

EXHIBIT E-4

CURRENT R&D EXPENDITURES AS A PERCENT OF OTHER CURRENT CAPITAL INVESTMENT



Source: Appendix Exhibit C-3

- Based on these data it appears that R&D in the chemical industry has declined progressively both as a share of sales and as compared with other capital investment. From a peak of 4.1 percent in 1962, chemical R&D spending as a proportion of sales dropped to 2.9 percent in 1981. For the same period, chemical R&D as a proportion of other capital investment fell from 74.4 percent to 39.9 percent. The surge in R&D spending coupled with a drop in real capital investment projected for 1981 through 1985 is expected to increase the R&D/Capital Investment ratio. However, the increase to 49.4 percent will not fully restore past declines.

- The relative decline of R&D spending in the chemical industry is similar to the pattern for industry as a whole. From these data, chemicals do not appear to be specially affected by regulatory or non-regulatory influences.

Generally, total real R&D expenditures by the chemical industry were flat or declining from the mid 1960's to the mid 1970's. After 1973, real R&D spending grew more rapidly and this trend is expected to continue. Notwithstanding this surge, R&D has continued to decline both as a proportion of sales and in relation to other capital investment.

The trends in the chemical industry are broadly similar to those of all industries combined. On the surface this would indicate no special adverse effects on innovation in the chemical industry. However actual effects on innovation can only be assessed after considering possible shifts in the distribution of R&D funds to new product research.

4. New Product Spending by SIC 28

Not all R&D is innovative in the sense of generating new products. An important research effort is improving the efficiency of production. Additionally, some R&D is denoted to bringing out new brands of products already on the market.

The purpose of isolating new product spending by the chemical industry is to identify the portion of R&D oriented toward producing new chemical substances to new chemical formulations using new chemical entities. In other words, the purpose is to identify the innovative component of chemical R&D that might be affected directly by section 5 of TSCA.[48]

5. Industry Data on New Product R&D

Data on the allocation of R&D expenditures to process (efficiency), existing products (new brands) and new products (innovation) is scarce. The only consistent series is provided by McGraw-Hill.[49] Because the question on allocation of R&D was not regularly included in the annual survey until 1973, before that year, data are available only for 1966 and 1971. Planned spending for 1981 is also included.

Exhibit E-5 shows the proportion of all industry[50] R&D spending that went to process (efficiency), existing products (brand), and new products (innovation).

- Generally the trend has been toward greater emphasis on process as compared with product R&D spending. Between 1971 and 1981, process R&D grew from 12 to 17 percent of total R&D.

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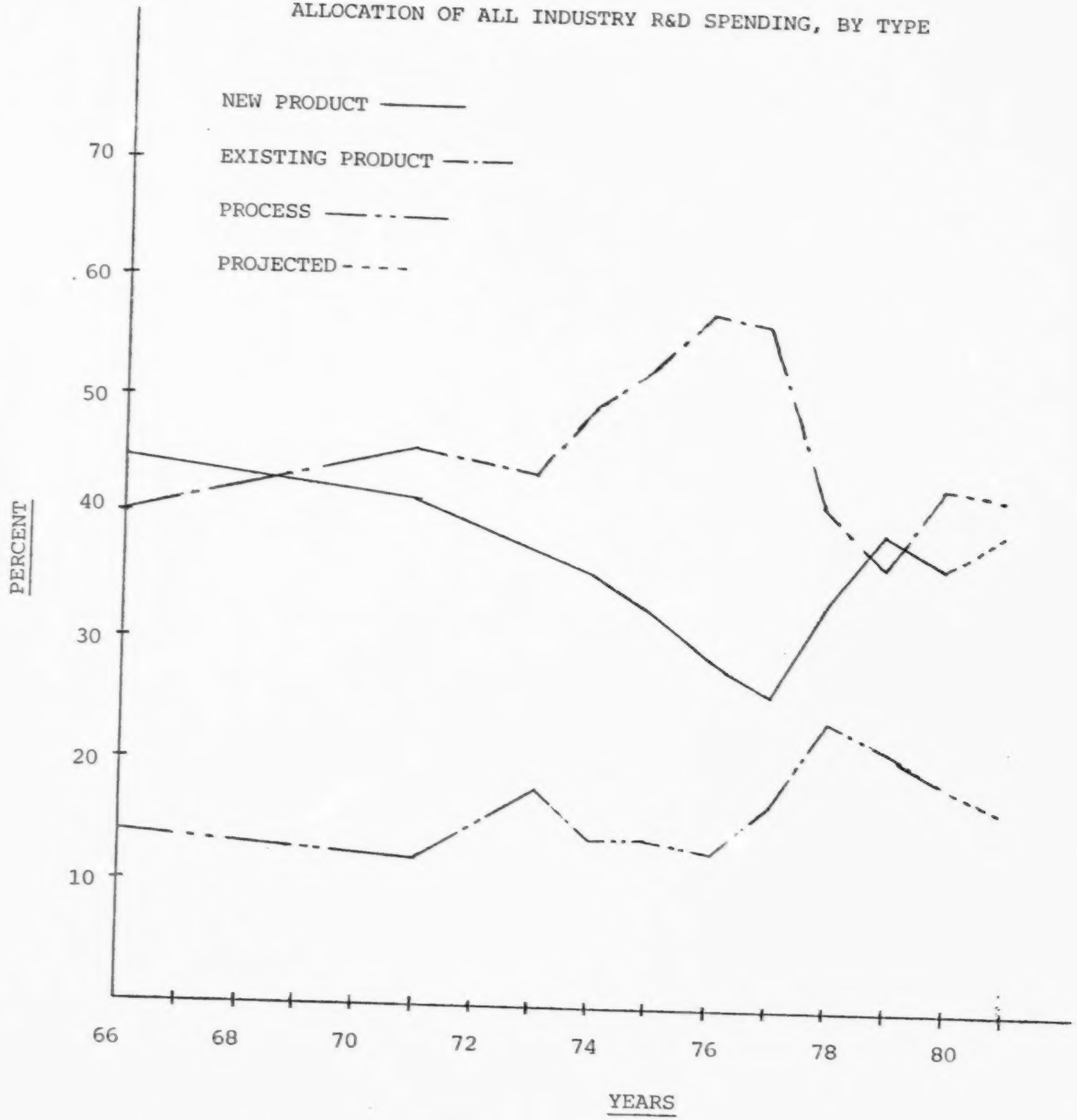
[48] TSCA section 5 covers new chemical substances and significant new uses of existing chemicals, although it is not clear yet how the latter authority will be used. Various aspects of existing chemicals are covered by TSCA section 5.

[49] Unlike NSF, McGraw-Hill does not distinguish spending by source. Consequently, the breakdown is for R&D expenditures by both government and industry for research conducted in company facilities.

[50] Non-manufacturing is excluded. However non-manufacturing accounted for less than five percent of the 1980 R&D spending in the McGraw-Hill survey.

EXHIBIT E-5

ALLOCATION OF ALL INDUSTRY R&D SPENDING, BY TYPE



Source: Appendix Exhibit C-4

- Within the product category there was an apparent shift toward existing products during the early 1970's. However this trend has reversed somewhat since 1978.
- None of these changes has been very large.

The reasons underlying these trends are not clear. It is possible that the marginal costs of the three different types of investment differ. For example, if product R&D generally requires a greater concomitant expenditure on capital equipment, product R&D may appear more expensive on the margin. Cost differentials together with capital availability and general economic conditions may be at least partially responsible for any shift from product to process R&D spending. However, such an examination is beyond the limited scope of this study.

In contrast to all industry, the chemical industry has included some pronounced shifting among categories. (See Exhibit E-6).

- The proportion of R&D spent on process approximately doubled during the 1970's (from seven percent in 1971 to 18 percent in 1981).
- At the same time expenditures shifted from new to existing products; new and existing products practically switched in relative importance. This shift, which does not appear to be reversing, began in 1974.

NSF data for 1979 are available for crosschecking the McGraw-Hill distribution. In 1979, NSF asked companies to break down total R&D (company and government) into the proportion spent for product and for process.[51]

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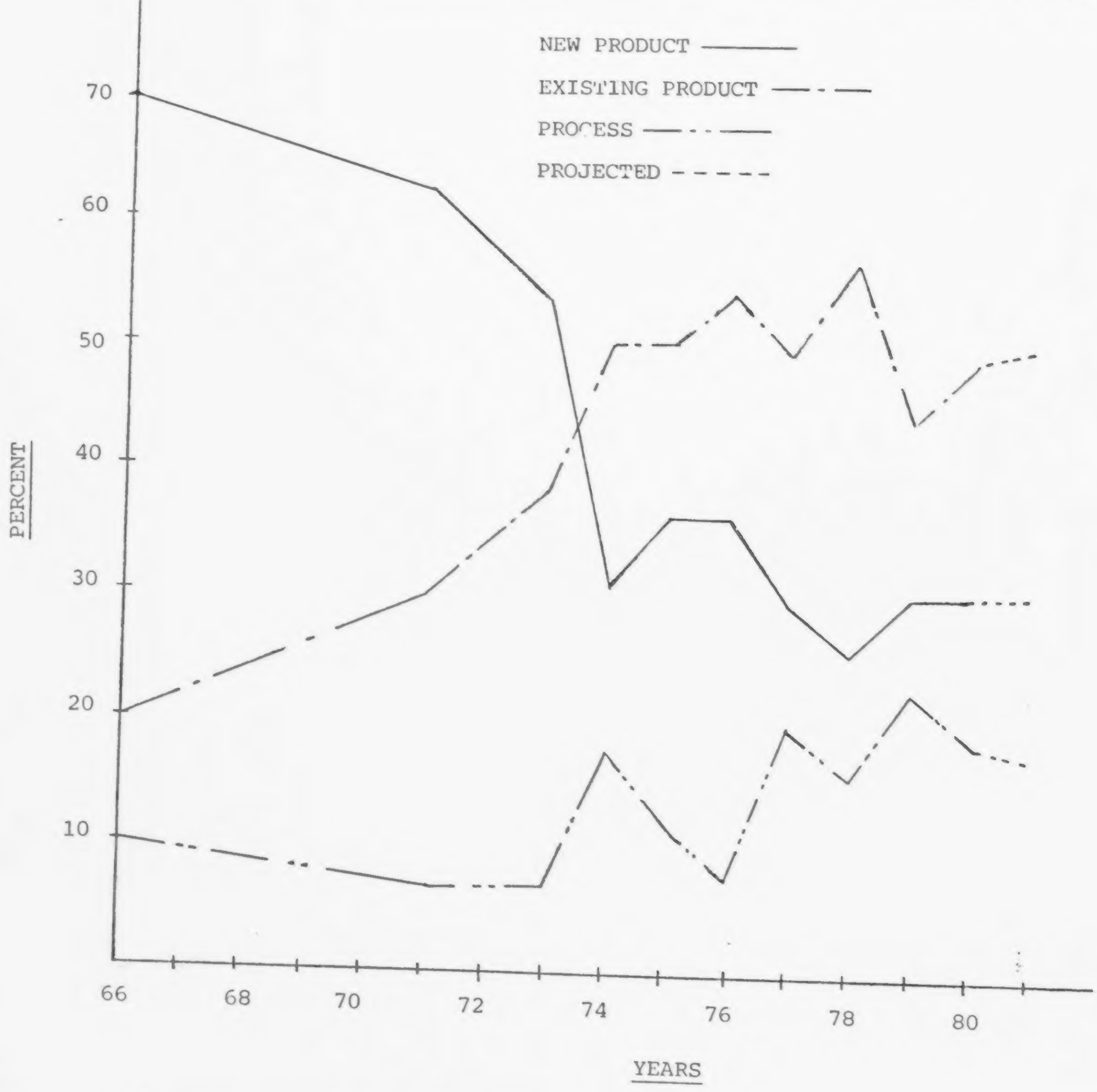
[51] The NSF data exclude basic research which was approximately nine percent of R&D and unclassifiable research (12 percent for the chemical industry in 1979).

EXHIBIT **E**-6

ALLOCATION OF CHEMICAL INDUSTRY R&D SPENDING, BY TYPE



Source: Appendix Exhibit C-4

Their findings (75 percent product and 25 percent process R&D in the chemical industry) are very similar to the McGraw-Hill results (76 percent and 23 percent respectively).

The NERA data show a somewhat different allocation. NERA found 1979 spending on process to be 41 percent, and product to be 59 percent (new product 42 percent and existing 17 percent).[52] It should be noted, however, that the NERA sample consisted mainly of larger companies and, unlike the NSF samples, is not considered representative of the industry.

On the surface, the McGraw-Hill information points to a pronounced shift away from new product spending by the chemical industry in 1974. New product spending dropped from 54 to 31 percent of total R&D expenditures in 1974. This in part results from a greater emphasis on process R&D after 1973 (from seven percent percent to 18 percent in 1974). The balance is due to a shift in spending from new to existing product R&D.

6. Interpreting Industry Data.

The ambiguity arises from common variations in the usage of the term "new product." Unfortunately the meaning relevant here (new chemical entity or formulation using a new chemical substance) is not universally employed.

The first time a company sells a product, the company may consider it a new product. However, from the market's standpoint, this company's first introduction may be a new brand rather than a new product. The definition depends on whether the item comprises a new chemical ingredient and/or a new formulation. For example, a company's introduction of generic laundry detergent may constitute a new product line for the firm but may only be a new brand in the market place.

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[52] Percentages after subtracting basic research (6.4 percent of total) and unclassified (7.3 percent of total).

In contrast, modifications or improvements to existing brands may involve the use of a new chemical substance. Although a firm would probably classify this as R&D for existing products, for our purposes it constitutes new product R&D. Firms' breakdowns of R&D spending between new and old products may not be appropriate for the purposes of this analysis.

This point is highlighted by information collected for the CSMA study on chemical specialty manufacturers' products innovations. The CSMA survey distinguished new product from existing product innovations. Additionally, the survey described whether the innovation involved a new chemical formulation and/or a new chemical substance. The findings are presented in Exhibit E-7.

Chemical specialty manufacturers may not be representative of the entire chemical industry in the quantity or breakdown of product R&D spending. Nevertheless, the data illustrate some important features of product oriented R&D.

- There are important differences among chemical firms in what is meant by a new product. Ingredient suppliers consider only new chemical substances to be new products. Product manufacturers who supply final products (e.g., hairspray) use a broader definition. (Heiden and Pittaway 1982, p. I-5)
- Among product manufacturers, new product "innovations" may be merely new brands to the company. Although new product innovations do not necessarily involve any new chemical formulation, existing products must involve at least a new formulation to be considered an innovation. (Heiden and Pittaway 1982, p. II-11)
- For product manufacturers, it is possible for at least as many new formulations and new chemical substances to result from existing as new product

EXHIBIT E-7

PRODUCT INNOVATIONS BY CHEMICAL SPECIALTY MANUFACTURING FIRMS

	1976		1978		1979		1980		1981	
	New	Existing	New	Existing	New	Existing	New	Existing	New	Existing
A. Product Manufacturers										
Total Number of Products	129	72	160	115	120	115	134	101	143	113
Number that are New Brands (Percent of Total Products	47 (36.4%)	0 (0%)	57 (35.6%)	0 (0%)	19 (15.8%)	0 (0%)	23 (17.2%)	0 (0%)	28 (19.6%)	0 (0%)
Number that are New Formulation (Percent of Total Products)	60 (46.5%)	72 (100%)	85 (53.1%)	115 (100%)	80 (66.7%)	73 (100%)	83 (61.9%)	101 (100%)	81 (56.6%)	113 (100%)
o Number with First Use Ingredients (Percent of New Formulation)	19 (31.7%)	22 (30.6%)	18 (21.2%)	45 (39.1%)	18 (22.5%0	24 (32.8%)	29 (34.9%)	36 (35.6%)	26 (32.1%)	25 (22.1%)
o Number with New Chemical Substances (Percent of New Formulation)	3 (5.0%)	3 (4.2%)	0 (0%)	1 (0.9%)	3 (3.8%)	3 (4.1%)	0 (0%)	0 (0%)	8 (9.9%)	2 (1.8%)
B. Ingredient Manufacturers										
Total Number of Products	163	0	173	0	119	0	124	0	133	0
Number with New Chemical Substances (Percent)	163 (100%)	0 (0%)	173 (100%)	0 (0%)	119 (100%)	0 (0%)	124 (100%)	0 (0%)	133 (100%)	0 (0%)

Source: Heiden and Pittaway 1982, Exhibits II-2 and II-3.

> R&D. In neither case does the proportion of innovations containing new chemical entities exceed six percent.(Heiden and Pittaway 1982, p. II-10)

The available data on R&D spending combine expenditures by product manufacturers and ingredient suppliers in the chemical specialties as well as other segments of the chemical industry. We would like to focus primarily on ingredient suppliers in each segment of the chemical industry because these firms are the primary developers of new chemical substances. New chemical substances, in turn are the major target of TSCA section 5 at this time.[53]

Unfortunately, we do not know how much of aggregate R&D expenditures were made by ingredient suppliers. Although the CSMA data may be representative of the distribution of firms by type for the chemical specialties segment, there is no reason to believe that the proportion of ingredient suppliers is similar in other segments of the chemical industry. Thus the CSMA data is of little use for breaking out the relative proportion of ingredient suppliers in the whole chemical industry.

Even if we knew the relative number of ingredient suppliers, we still could not identify the proportion of R&D expenditures for which this group of firms accounted. Neither CSMA nor any other data source indicates what proportion of R&D spending is made by ingredient suppliers. Except in the unlikely case that all firms (regardless of size or type of business) spend the same amount on R&D, it is not possible to break down aggregate R&D spending on the basis of the distribution of the number of firms.

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[53] TSCA section 5 also covers significant new uses of existing chemicals. However, it is not yet clear how this authority will be used.

Despite these limitations, the CSMA data do help us interpret R&D spending trends. For example, CSMA data show that in both the new and existing product categories, the aggregate R&D expenditure data includes spending on new formulations that may or may not incorporate new chemical substances. Ideally, only R&D spending for those formulations containing new chemical substances (or significant new uses of existing chemicals) and covered by section 5 of TSCA should be included in our series. However, because the CSMA data, as noted above, cannot be used directly to adjust R&D data, we do not feel that formulations subject to section 5 can be accurately separated. Consequently, our series overstates new product R&D spending by the amount, devoted to new formulations that do not include a new chemical substances (or significant new uses of existing chemicals).

In addition, the CSMA data show that aggregate industry data on R&D spending to develop new products may include spending for new brands as well as expenditures for new chemical entities and new formulations (regardless of whether they incorporate new chemical substances). Moreover, reported R&D spending on existing products may include expenditures for new chemical substances and new formulations (with or without new chemical entities) but it appears to exclude spending on new brands.

In other words, R&D spent on either new products or existing products may include spending for products subject to TSCA section 5: new chemical substances and new formulations with new chemical substances (or significant new uses of existing chemicals.) Likewise, both existing and new product R&D spending include expenditures on new formulations that do not include new substances and are not subject to TSCA section 5. However, only R&D spending for new products includes expenditures for new brands which definitely are not covered by section 5.

New product R&D spending includes two types of expenditures that are not subject to section 5 (new brands and new formulations that do not have new chemical substances). On the other hand existing product R&D contains only one type of spending not subject to TSCA section 5 (new formulations not containing new chemical entities). It is not clear which category actually incorporates more spending on new chemical substances.

7. Determining the Proportion of New Product R&D/SIC 28

Because of the inherent imprecision of the data, we established a range for the proportion of new product R&D rather than estimating a precise percentage. To get the maximum estimate (upper bound) of the proportion of R&D expenditures spent on new chemical substances (i.e., new products) we used total product R&D expenditures (i.e., total R&D less process R&D). As noted above, this estimate includes an undetermined amount of spending on products not subject to TSCA section 5.

As mentioned above, it is not clear which of the following categories contains more spending in new chemical substances: data reported as R&D spending on new products; or data reported as R&D spending on existing products. Of the two, the estimate of existing product R&D spending is larger. To lessen the chance we have left out relevant R&D spending, we selected existing product R&D spending as the minimum estimate (lower bound) of R&D expenditures on new chemical substances (i.e., new products).

Exhibit E-8 shows how the range of new product R&D spending has changed over time in the chemical industry. From this perspective, it is not clear that a dramatic shift away from new product spending has occurred. The range for new product spending narrowed substantially during the 1970's. The reduction in the range resulted partially from a decline in the maximum

EXHIBIT E-8

PROPORTION OF R&D SPENT ON NEW PRODUCTS BY THE CHEMICAL INDUSTRY

Year	Range of Percentage
1966	20% - 90%
1971	30% - 93%
1973	39% - 93%
1974	51% - 82%
1975	51% - 88%
1976	55% - 92%
1977	50% - 80%
1978	58% - 84%
1979	45% - 76%
1980	50% - 82%
1981 (planned)	51% - 82%

Source: : McGraw Hill Publications

possible percentage going to new product R&D. Since the maximum is based on total product spending, this means R&D process spending increased. However, at the same time, the minimum percentage going to new product spending increased. (This, of course, is an artifact of the choice of existing product R&D as the lower bound.)

In other words, spending on developing new chemical formulations and substances has not necessarily declined because a larger portion of R&D goes to process spending. The evidence suggests an intensifying interest in reformulating and improving existing products. The reduction in what McGraw-Hill termed new product spending may reflect a reduction in development of entirely new items. Alternatively, the shift may equally imply a reduction in brand proliferation as firms retrench in existing product lines.

Exhibit E-9 presents the estimates of new product spending (in real 1981 dollars) implied by the distribution of R&D shown in Exhibit E-8. The estimates are simply the product of the new product spending percentages and real company R&D expenditures by the chemical industry. Strictly speaking, the allocation percentages should be applied to R&D spending from all sources. However, the government contribution has consistently been small (10 percent of the total). The potential distortion is negligible when compared to the size of the range.

Based on the data in Exhibit E-9, it appears that in five of the seven years after after 1974 real spending on new products increased. However, declines occurred in 1977 and 1980.

EXHIBIT E-9

REAL NEW PRODUCT SPENDING BY THE CHEMICAL INDUSTRY

(1981 Dollars)

Year	Millions of 1981 Dollars
1966	$615.2 - $2,768.4
1971	$992.1 - $3,075.5
1973	$1,356.2 - $3,233.6
1974	$1,905.9 - $3,064.3
1975	$1,958.9 - $3,380.1
1976	$2,218.7 - $3,711.3
1977	$2,047.5 - $3,276.0
1978	$2,409.3 - $3,489.4
1979	$2,958.0 - $3,306.8
1980	$2,329.0 - $3,819.0
1981 (planned)	$2,563.2 - $4,077.9

Source: : ICF estimates.

To further refine our estimates of new product spending, we have tried to separate R&D spending on new drug and medicine products from the rest of the chemical industry's expenditures. The disaggregation was based on R&D information collected by PMA.

As discussed earlier, PMA conducts an annual survey of its membership which accounts for approximately 90 to 95 percent of all pharmaceutical production. Pharmaceuticals, in turn, comprise the majority of R&D spending in drugs and medicines. Although real pharmaceutical R&D spending reported by PMA as a proportion of R&D spending by drugs and medicines in the NSF series has declined over time, the current ratio is 0.80.

PMA does not break R&D spending for new product, existing product, and process into naturally exclusive categories. From 1972 to 1979, PMA provides data showing the proportion of all R&D that was devoted to new products as compared with existing products. Elsewhere, PMA shows the proportion of all R&D that was for process development for manufacturing and quality control. PMA does not indicate how much of process expenditures were spent on existing as compared with new products. To combine the two independent pieces of information we assumed that, after subtraction of process R&D, the remaining expenditures were divided among new and existing products in the same proportions as reported for total R&D.

This percentage allocation was applied to the NSF data series (as updated here) to determine the amount of real R&D spending (1981 dollars) in each category.

In other words, total R&D spending by the drugs and medicines group was distributed as follows:

$$R+D_T = [\alpha(R+D_T)] + [\beta(1-\alpha)(R+D_T)] + [(1-\beta)(1-\alpha)\ (R+D_T)]$$

Where

$R+D_T$ = total R&D spending by drugs and medicines.
α = proportion of total R&D spent on process.
$(1-\alpha)$ = proportion of total R&D spent on products.
β = proportion of total R&D spent on new products.
$(1-\beta)$ = proportion of total R&D spent on existing products.

The results for drugs and medicines (Exhibit E-10) show that:

- In contrast to the rest of the chemical industry, the drugs and medicines group has increased the proportion of R&D spent on new products.
- Spending on both process and existing product R&D declined.

EXHIBIT E-10

DISTRIBUTION OF R&D SPENDING IN THE DRUGS AND MEDICINES SEGMENT
(Millions of 1981 Dollars)

Year	Process		New Product a/		Existing Product a/	
	Amount	%	Amount	%	Amount	%
1972	$143.5	12.2	$787.9	69.0	$244.6	20.8
1973	$127.9	10.0	$912.1	71.3	$239.2	18.7
1974	$127.8	9.4	$978.2	71.7	$257.1	18.9
1975	$148.3	9.8	$1074.5	71.0	$290.6	19.2
1976	$152.0	9.5	$1182.2	73.9	$265.6	16.6
1977	$148.7	9.3 b/	$1178.2	73.7 b/	$271.8	17.0 b/
1978	$150.8	9.2	$1206.7	73.6	$282.0	17.2
1979	$150.9	8.8	$1287.8	75.1	$276.1	16.1
1980 c/	$152.6	8.4	$1382.7	76.1	$281.6	15.5
1981 c/	$155.1	8.0	$1495.1	77.1	$288.9	14.9

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a/ Assumed to the same proportion of Product Category as proportion reported for all R&D.
b/ Estimated on basis of average annual change between 1976 and 1978.
c/ Estimated by extrapolating average annual rate of change 1972-1979.
Source: NSF 81 and PMA.

Exhibit E-11 shows the range of spending on new products after drugs and medicines has been subtracted. From the lower bound (based on total existing product R&D) we subtracted drugs and medicine existing product R&D. From the upper bound (based on all product R&D) we subtracted drug and medicine new product and existing product R&SD. The impact of separating out drugs and medicines has been:

- to reduce the range of new product spending, principally by lowering the upper bound,
- to lower significantly the estimate of new product spending.

EXHIBIT E-11

REAL NEW PRODUCT SPENDING BY
THE CHEMICAL INDUSTRY EXCLUDING DRUGS AND MEDICINES
(1981 Dollars)

Year	Millions of 1981 Dollars
1973	$1,116.8 - $2,082.3
1974	$1,648.8 - $1,832.0
1975	$1,668.3 - $2,015.0
1976	$1,953.1 - $2,263.5
1977	$1,775.7 - $1,826.0
1978	$2,127.3 - $2,000.7 a/
1979	$1,681.9 - $1,742.8
1980	$2,047.4 - $2,155.3
1981 (planned)	$2,247.3 - $2,293.9

Source: ICF estimates.

C. COMPARISON OF PRE- AND POST-TSCA PERIODS

One reason for examining new product spending is to identify if a major shift in new product R&D expenditures may have coincided with the effective date of section 5 of TSCA. Because section 5 imposes additional costs on new product development, the regulation may discourage innovation. If so, a reduction in R&D expenditures might be observed when section 5 went into effect (1979).

The first step toward comparing new product spending before and after TSCA was dividing the series into two time frames. Pre-section 5 was represented by the period prior to 1979. Post-section 5 included 1979 and after.

Having split the series, the problem was to determine whether post-section 5 new product spending differed from what it would have been in the absence of section 5. We used two approaches to assess whether a significant shift in new product R&D coincided with implementation of TSCA's section 5. The two methods were fitting of a trend line, and extrapolating pre-1979 R&D spending, and comparing representative average R&D spending before and after 1979.

1. Fitting A Trend Line

Fitting a trend line is a method of extrapolating year to year data against which to compare actual R&D spending after section 5. The growth rate for the trend line considers each data point in the period. In a linear analysis, essentially, a straight line is fitted between the series of data points that results when spending is plotted as a function of time. The growth rate is the slope of that trend line.

In fitting the trend line we used the mid-point of the R&D spending range for the chemical industry excluding drugs and medicines. Actual new product spending for 1974 through 1978 was used to determine the growth rate for the projected series.[54] The actual spending data were then compared with what would have been expected if there were no year to year variation from the implicit trend.

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[54] We did not use data for 1973, which is the only year of fully adjusted data we have prior to 1974. The reason for excluding 1973 is that between 1973 and 1974 a dramatic shift occurred in the distribution of R&D spending by type. This shift toward greater process R&D has not reversed for the entire 1974-1981 period. Consequently, we believe that the 1973-1974 shift represents more of a structural change than a normal year to year observation. Moreover, as the shift coincides with a sharp rise in oil prices, it is likely related to economic factors rather than TSCA section 5.

The results of this exercise are shown in Exhibit E-12. The findings show a drop in R&D spending after section 5. However, this decline in R&D spending is not statistically significant for two reasons. The amount of the deviation from trend in 1979 and 1980 is not large, when compared to the amount of deviation from trend experienced between 1974 and 1978. To test the statistical significance of the result we constructed the model

$$R\&D_t = b_o + b_1 \text{ (Year-1973)} + b_2 D \text{ (Year-1973)}$$

where D = 1, if the year is 1979 or 1980, and D=0 in other years. The results showed $b_o = 1699.1$, $b_1 = 68.8$, and $b_2 = -34.8$. Then we calculated the t-statistic based on the hypothesis that there had been no change from the previous trend and found that we could not reject this hypothesis (t = .88).

EXHIBIT E-12

TREND ANALYSIS OF REAL NEW PRODUCT
R&D SPENDING BY THE CHEMICAL INDUSTRY
(Millions of 1981 Dollars)

Year	Actual	Trend Line Estimates a/
1974	$1740.4	$1789.8
1975	$1841.7	$1850.4
1976	$2108.3	$1911.1
1977	$1800.9	$1971.7
1978	$2064.0	$2032.3
1979	$1712.4	$2093.0
1980	$2101.3	$2153.6
1981 (planned)	$2270.6	$2214.3

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a/Trend line estimated from actual data, 1974-1980.
R&D (millions of $) = 1699.1 + 68.8 X (Year-1979) - 34.8 X D X (Year-1973), where D equal 0 in 1974 to 1978 and D = 1 in 1979 and 1980.

Source: ICF estimates.

In addition to our finding of no statistically significant deviation from trend, it must be noted that extrapolation by a trend line does not really reflect what would have happened in the absence of TSCA section 5. The normal year to year variation results from a convergence of factors whose interaction is not captured by simply fitting a trend line. (META 1981)

2. Estimating Representative Average R&D Spending

Another approach to assessing section 5's potential effects involves comparing average R&D spending before and after section 5 took effect. Provided the data are adjusted for inflation and real growth in the chemical industry, the pre-section 5 spending figure would comprise a baseline for assessing post-section 5 spending. To estimate a figure of baseline R&D spending, we averaged R&D expenditures in 1981 dollars for 1974 through 1978. This approach was taken because:

- 1978 may not be representative of a good baseline because of potential transition phase distortions.
- No clear trend was evident between 1974 and 1978; the spending vacillated year to year.
- A big shift in 1974 occurred; years prior to 1974 were excluded to eliminate the distorting influence of factors precipitating the 1974 change in spending. (ICF n.d.)

A similar approach was taken to estimating R&D expenditures after section 5 went into effect. New product R&D expenditures for 1979 through 1981 were averaged to achieve the estimate. In this case, the average approach was adopted mainly to minimize potential transition phase problems.

In doing the averages, we used the midpoint of the R&D spending range for each year. As in the trend analysis, we used real R&D spending in 1981 dollars. Consequently, the distorting effects of inflation were removed.

We also adjusted the data for real growth in the chemical industry. We wanted to eliminate the effect of correlation between R&D expenditures and industry size so that we could observe better the potential regulation effects. To make the adjustment we used an index of real growth in chemical sales.

The Adjusted series is shown in Exhibit E-13.

EXHIBIT E-13

ADJUSTED REAL NEW PRODUCT SPENDING BY THE CHEMICAL INDUSTRY (EXCLUDING DRUGS AND MEDICINES) a/

Year	Millions of 1981 Dollars
1974	$2,333.0
1975	$2,498.9
1976	$2,599.6
1977	$2,156.8
1978	$2,419.7
1979	$1,754.5
1980	$2,242.6
1981 (planned)	$2,270.6

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a/ Adjusted for inflation using the GNP deflator (1981 = 100) and for real growth in chemical sales (1981 = 100).

Source: ICF estimates.

Exhibit E-14 gives our estimates of real adjusted R&D spending both before and after section 5 took effect. The baseline R&D expenditures estimate is $2401.6 million as compared with $2089.2 million after section 5. Although these results seem to indicate a decline in R&D spending after TSCA section 5 took effect, the drop is probably not significant. The difference of means test that we applied resulted in a t-statistic of 1.4084 which for the number of degrees of freedom was not significant at the 90 percent level.

EXHIBIT E-14

ADJUSTED REAL NEW PRODUCT SPENDING BY THE CHEMICAL INDUSTRY BEFORE AND AFTER SECTION 5

(Millions of 1981 Dollars)

	Midpoint
Baseline (before section 5; average 1974-1978)	$2401.6
After section 5 (average 1979-1981)	$2089.2

Source: ICF estimates.

3. Conclusions

Despite the numerous assumptions required, the differences in the data, and the complexity of the problem, the two approaches used here give similar results. On the basis of both the trend fitted extrapolation and the comparison of representative averages were found:

- Actual R&D spending by the chemical industry (excluding drugs and medicines) declined relative to the baseline in 1979 (the year TSCA became effective).
- The magnitude of the drop was not significant when compared with normal year to year variation in the data.

In addition, the trend fitted extrapolation indicates that by 1981 planned R&D spending will exceed projected R&D expenditures. This reinforces the notion that the decline relative to baseline in 1979 was not out of the ordinary. At any rate it appears that the decline in spending relative to baseline is a temporary not a permanent phenomenon.

Even the small and temporary shift noted here cannot be attributed exclusively to TSCA section 5. In addition, in any evaluation of R&D spending data, it is important to bear in mind that:

- Coincidence is not causality. Changes in spending that occurred when section 5 went into effect may have been induced by unrelated factors, e.g., profitability, oil-price shocks of 1979, or tax code changes.

- R&D spending is not the same as innovation. Although we have tried to isolate new product spending (which is not precisely new chemical spending), we are still a step removed from predicting or evaluating innovation. The relationship between the quality and quantity of innovation and the level of new product R&D spending is still unknown.

- The timing of spending changes may not coincide with section 5's effective date. To the extent the chemical industry anticipated section 5, the effects on innovation may be felt in one or more years prior to 1979. Alternatively, if innovation (and R&D spending) are multi-year processes TSCA section 5's impacts may not be seen until several years after 1979.

4. Transition Phase

The likelihood of a transition phase complicates efforts to relate new product spending changes and section 5 of TSCA. The transition phase may precede section 5's effective date, follow the effective date, or both.

Major legislation such as section 5 of TSCA is widely debated prior to enactment. Industry knows generally the provisions and effective date of the law. Adjustments to comply with or minimize the effect of section 5 may have begun years in advance.

For example, high new product spending during 1978 may have been induced by section 5. Chemical companies may have pushed their research schedules forward to complete projects in advance of the regulations effective date. The incentive for such behavior is that pre-TSCA introductions of new chemical substances would be exempt from the pre-manufacture notification process. The 1979 drop in spending may merely be a return to trend.

To the extent 1978 spending was section 5 induced, the extrapolation based on 1978 is distorted. The expected spending range would be overstated and the potential effect of section 5 overstated. The result would be an erroneous impression that TSCA depressed spending rather than simply shifted the timing.

Although industry can anticipate the general form of legislation, it may not be completely familiar with all details. Unfamiliarity with reporting procedures and requirements may make compliance more expensive initially. This may be especially true of smaller firms that may be less accustomed to government regulations and do not have legal and technical expertise to adjust quickly to a new regulatory regime. In this case, adverse impacts experienced immediately after a change in legislation may overstate the long term effects.

For example, an alternative view of the 1979 drop in new product spending is that 1979 was an adjustment year. As firms become more accustomed to section 5, they resumed spending on new product R&D.

Actually section 5 may have engendered both anticipation and unfamiliarity effects. Consequently it is very difficult to assess the duration of the transition period or whether it has a large enough impact to matter.

APPENDIX F

HEALTH EFFECTS OF EPA REGULATORY ACTIONS CONCERNING NINE PMN CHEMICALS

The following section briefly discusses the likely health implications of regulatory actions that EPA has taken on nine PMN chemicals where agency health concerns resulted in voluntary actions on the part of manufacturers to reduce exposures. These actions ranged from simple revisions of Materials Safety Data Sheets (MSDS) to requests for lengthy, in some cases apparently permanent, suspensions of Agency review for substances where it had become clear that EPA had serious reservation about health risks.

The discussions which follow each contain a brief description of the PMN substances, the nature of the health concerns raised by EPA, the regulatory history of the PMN and an assessment of the likely net health impacts of EPA's decision. In several of the cases, quantitative estimates of risk reduction are not possible because of uncertainties about exposure levels, dose-response relationships, or lack of knowledge about the toxic effect of substitutes for the PMN chemicals.

A. PMN'S F, G, AND H

These three chemicals are closely related crosslinking agents for use in coatings. The manufacturer (they were all made by the same firm) intended to produce over 1,000 kilograms per year of each substance. EPA estimated that about 6 workers would be exposed to the PMN substance during production and formulation of the product and another 100 workers would be exposed during application of the coatings. Exposure levels were estimated to be between 8.0 and 0.01mg/M^3 in air during application with average levels being about 0.1 mg/M^3. The major concern regarding these substances was that they were intended to decompose during use and would be expected to decompose upon exposure to moisture to yield one of the starting materials, a known animal carcinogen. EPA repeatedly asked the manufacturer to supply information on worker exposures and the toxic properties of likely substitutes. Upon realizing the depth of EPA's concern, the manufacturer requested that the review period be suspended and no Agency action has since been taken in this case.

Despite the fact that animal tests indicate that the starting material in question is a relatively potent animal carcinogen, simple calculations suggest[55/] that because of the relatively low exposure levels, the number of cancers prevented by EPA's action is quite small, on the order of 1×10^{-8} - 1×10^{-6} per exposed worker per year of exposure. It should be noted, however, that the PMN substance was judged to be more toxic then 10 of 16 of its possible substitutes, and significantly less toxic than only one of its possible substitutes, so that in this case, EPA action probably resulted in a net substitution of less toxic substances for a more toxic one.

B. PMN I

This substance is a low molecular weight polymer. The manufacturer intended to produce up to several thousand kilograms/year for use as an

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[55/] These calculations assume air exposures between 0.01 and 0.8µg/m^3 for 24 hours per worker per year (EPA estimate), 100 percent conversion of the PMN substance to the carcinogenic starting material and 100 percent absorption of inhaled vapors.

automobile lubricant additive. The agency estimated that about 12-30 workers would be exposed to the pure substance during production and as many as 65,000 consumers (auto mechanics) would experience dermal exposure to the substance diluted in crankcase lubricant for up to 250 hours per year. The manufacturer had tested the substance for toxicity prior to filing the PMN and found that, while the pure substance was a skin and eye irritant in rabbits, it was a relatively weak acute toxin. EPA was concerned that expected breakdown products of the material could be skin sensitization agents. The manufacturers voluntarily suspended the review period while sensitization tests were performed. The tests on the pure substance proved to be negative. Examination of the chemical structure of the PMN substance indicated that little of the toxic breakdown product would actually be formed during use. The substance was therefore "dropped" and production was allowed to begin.

It is difficult to estimate the health impacts associated with EPA action in this case. The slight delay in introduction of the chemical may have prevented some small number of cases of skin and eye irritation. Since the health effect associated with the use of substitute additives was not known, the net effect on health cannot be determined. Of course, had the substance been found to be a skin sensitizer, and there were reasonable grounds to suspect that it was, considerable direct health benefits might have been realized by EPA's action.

C. PMN J

The PMN substance in this case is an organic salt mixture. It was intended to be imported as an ingredient in a neutral metal cleaning formulation in quantities of over 5,000 kilograms per year. Approximately 5 workers would have received intermittent dermal exposure to the pure substance during formulation, and as many as 500 workers would have been exposed to dilute water solutions of the PMN substance during use. The pure PMN substance was tested and found to be a moderately potent eye irritant. The overall level of concern, however, was relatively low because of the low production volume and low concentration of the substance in cleaning baths during use. EPA suggested, however, that the substance be labeled to prohibit use with certain cleaning fluids, because of the possible formation of a carcinogenic derivative. The company agreed and amended the TSDS (technical services data sheet) to state that the product should not be used in conjunction with certain cleaning fluids.

Little evidence exists to indicate how often the PMN substance would have been used with the problematic cleaning solutions had the TSDS not been altered. To what extent the TSDS resulted in changes in user behavior, or the extent to which worker exposure was changed by EPA actions is not clear. A simple worst-case exposure calculation[56] suggests that the reduction in health risks brought about by the labeling was quite small, between 10^{-5} and 10^{-2} total cases of cancer prevented per year of use of the PMN substance among all exposed workers, assuming that the use of the substance in conjunction with problematic cleaning solutions was completely abolished by the TSDS revision. This may not have been the case because of the large number of cleaning formulations in use.

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[56] We assumed workers were exposed to 10-100 ml per day of bath fluid containing 0.1-1.0 percent PMN substance for 240 days per year, that 10-100% of the PMN substance was converted to nitrosamine and that 10-100% was absorbed through the skin.

D. PMN'S K, L, AND M

These three substances are closely related fabric dyes, intended for import in quantities of < 10,000 kilograms per year by a major dye manufacturer. Approximately 35 workers per year were expected to be exposed to these substances, 6 to the solid powder during dyebath preparation and 29 to freshly-dyed fabric and dyebath liquid. The substances were to have been released to privately and publicly owned water treatment works in significant amounts and could have been released into drinking water. All three of the substances have in common a chemical structure which could be expected to break down under ambient conditions to yield at least two families of metabolites which were structurally similar to known human and animal carcinogens. During the review period, EPA made repeated requests to the importer for data concerning the metabolism of the PMN substance and related chemicals. When it became clear that little was known about these substances, EPA suggested that mutagenesis studies be performed on the three chemicals. A formal 5(e) order was not drafted, but the Agency still has the substances on a 5(e) course should the submitter decide to resume the review period without submitting additional data. The importer requested that the review period be suspended and no further action has been taken as of this time.

By its action, EPA has delayed, pending the development of further information, the introduction into commerce of three substances which there is good reason to believe could pose substantial carcinogenic risk to exposed individuals. Unfortunately, because of our lack of knowledge about the nature and amounts of the metabolites that would be formed and the carcinogenic properties of these metabolites, it is not possible to develop quantitative estimates of the number of cancers prevented. Again the lack of knowledge about the toxic properties of likely substitutes also affects our ability to perform quantitative benefit estimates.

E. PMN N

This chemical is an intermediate in the production of dyes for textiles and plastic resins. The manufacturer intended to produce this substance, in quantities of < 5,000 kilograms per year. Only four workers were expected to be exposed to the PMN substance during its synthesis and use. EPA's concern over the substance arose from the fact that several structural analogues to the PMN chemical had been found to be animal carcinogens and information supplied in the PMN which suggested that exposure levels might be high during one particular step in the production process. Subsequent discussion with the manufacturer indicated that substantial exposures were not likely to occur because standard company practice required the use of local exhaust ventilation and personal protective devices during handling of all dangerous substances. The company agreed, however, to revise the MSDS to include mention of the carcinogenic properties of the analogues of the PMN substance and the PMN was "dropped" from further review.

Since so few workers were exposed to the PMN chemical and since exposure levels were so low even without EPA's intervention, it is not likely that the revision of the MSDS produced anything but a very small decrease in the expected cancer risk for the exposed individuals. In fact, several recent epidemiologic studies of populations exposed to high levels of a close structural analogue to the PMN chemical, have found no increase in cancer incidence among exposed individuals. Thus the PMN substance may in fact pose even less of a carcinogenic risk to humans than the animal tests of analogue substances suggest.

F. SUMMARY AND DISCUSSION

Our analysis of these nine PMN submissions did not find any individual case in which EPA action prevented adverse health effect on the order of magnitude similar to those associated with the better-known occupational toxins or environmental pollutants. In the two instances (PMN's F, G and H and PMN J) where quantitative assessments of risk reduction were developed, the estimated number of cancer cases prevented is much less than one. In other cases (PMN's K, L, and M) where the Agency raised concerns about the carcinogenic properties of three textile dyes, it is likely that cancer risks to the exposed workers were also reduced. Although uncertainties concerning dose response relationships made quantitative assessments of risk reduction infeasible, it is possible that the magnitude of risk reduction in these cases could be larger than that for actions taken in the two previous cases. For the other case in which a suspect carcinogen was involved (PMN N) the exposure levels and the number of workers exposed were so low and the evidence for carcinogenicity in humans was so ambiguous that a confidence interval for our estimates of cancer risk reduction must include zero.

For PMN I, EPA's action delayed the introduction of the substance into commerce until results of animal testing indicated that the chemical was not a skin sensitizer. In this case it is difficult to estimate the benefits of the EPA's action, which would take the form of possible reduced incidence of skin and eye irritation during the delay before introduction, although the expected number of cases avoided is probably much greater than the number of cancers prevented in the previous examples.

The results of this analysis do not in and of themselves constitute an estimate of the benefits of the PMN program. The number of chemicals analyzed is not sufficiently large to give a statistically representative picture of new chemical introduction. It is not at all surprising that we did not encounter a vinyl chloride or a benzidine among our sample of nine chemicals since such high-volume and highly toxic chemicals will be introduced into commerce quite rarely. When they are introduced, the benefits of having the PMN process in place to "catch" them would be substantial. Also, the fact that the PMN program is in place decreases the likelihood that such very hazardous substance would be considered for introduction at all by manufacturers.

It is difficult to predict how hazardous the newly-introduced chemicals would have been over the period covered by this analysis in the absence of the PMN program, but we suspect that the deterrent effect of the program in preventing the introduction of such substances into commerce has been great. It is highly probable that the existence of the PMN program has resulted not only in the introduction of less hazardous chemicals than would otherwise have been introduced, but also in improvement in the measures taken to limit exposure when new chemicals are introduced. The benefits, in terms of reduced risks to human health that have resulted from the deterrent effects, are certainly much greater than the modest benefits which have arisen through the control of the nine chemicals analyzed here.

Finally, the benefits that we have estimated to have accrued from EPA's actions have taken the form in most cases, of cancers avoided. This is primarily because cancer dose-response extrapolation is relatively straightforward compared to assessing the likelihood of other adverse effects. In our professional judgment, it is probable that risk of other types of effects averted by these nine EPA actions to reduce exposure to toxic substances (such as idiosyncratic or hypersensitivity reactions to chemicals among the exposed populations or other effects not predicted by toxicity testing) would be much greater than the number of cancers prevented. Unfortunately, there is at present no way to estimate the magnitude of these effects.

APPENDIX G

SAMPLE OF EPA79, CMA79, EPA82, AND FINAL FORM

PROPOSED FORM

EPA United States
Environmental Protection
Agency

PREMANUFACTURE NOTICE

DOMESTIC MANUFACTURERS

When completed send this form to:

Document Control Officer
Office of Toxic Substances, TS-793
U.S.E.P.A.
401 M Street, S.W.
Washington, D.C. 20460

EPA USE ONLY
Date of receipt

GENERAL INFORMATION

The Premanufacture Notice form for domestic manufacturers is divided into the following parts:

- Part I – General Information
- Part II – Human Exposure and Environmental Release
- Part III – List of Attachments
- Part IV – Federal Register Notice
- Part V – Optional Data

The optional part (part V) is not included in this package. All data requested in the mandatory parts (parts I, II, III, and IV) must be reported to the extent they are known to or reasonably ascertainable by the submitter. This means that the submitter is expected to answer all questions to the best of his/her ability, including making reasonable estimates in cases where complete factual information is not available. If the submitter is unable to make a reasonable estimate (i.e., the data is not known and is not reasonably ascertainable), he/she should enter "NA" (not available).

In part I, the submitter is required to report the specific chemical identity of the new substance, regardless of whether the information is claimed as confidential. In accordance with proposed §720.20(f), the submitter may authorize another person to report the specific chemical identity in his/her behalf. The notice will not be valid until the specific chemical identity is received by EPA.

If the space on the form is not sufficient to adequately answer a question, the submitter may attach additional sheets. Identify any continuation by part, section, subsection, and item.

ASSERTING AND SUBSTANTIATING CLAIMS OF CONFIDENTIALITY

Read Appendix A, Instructions for Asserting and Substantiating Claims of Confidentiality, for information on how to claim and substantiate confidential business information included in this form or in attachments to the form. Claims of confidentiality must be made in accordance with sections I and II of these instructions. In addition, substantiation of all claims of confidentiality must be made in accordance with section IV of these instructions. If you claim any item in any attachment to this form confidential, see SPECIAL INSTRUCTIONS for attachments. Appendix A, Section II, Appendix B "Examples," provides additional guidance for asserting and substantiating claims of confidentiality.

In accordance with sections I and II of the confidentiality instructions, claims of confidentiality must be made by using the following six categories.

A. MANUFACTURER'S IDENTITY

A claim of confidentiality for Category A, Manufacturer's Identity, automatically includes items 1, 2, and 3 in part I, section A.

B. SPECIFIC CHEMICAL IDENTITY

A claim of confidentiality for category B, Specific Chemical Identity, automatically includes items 1, 2, and 3 in part I, section B.

C. PRODUCTION VOLUME

A claim of confidentiality for category C, Production Volume automatically includes item 1 in part I, section D. These items do not need to be individually claimed.

D. USE DATA

A claim of confidentiality for category D, Use Data, automatically includes item 2 in part I, section D. These items do not need to be individually claimed.

E. PROCESS INFORMATION

A claim of confidentiality for category E, Process Information, automatically includes items in part II, section A, subsection 2. These items do not need to be individually claimed.

F. OTHER INFORMATION

No items on the form are automatically included in this category. Thus all claims for this category must specify category F.

GENERAL CERTIFICATION

I hereby certify to the best of my knowledge and belief, that:

- **a.** The company named in section A, item 1, intends to manufacture for a commercial purpose the chemical substance for which this notice is submitted, other than in small quantities for research and development, and that the substance is not excluded from premanufacture notification (40 CFR 720.13);
- **b.** All information entered on this Premanufacture Notice form is complete and truthful as of the date of submittal; and
- **c.** I am submitting with this form all test data in my possession or control concerning effects of the substance on health or the environment and a description of any other data known to or reasonably ascertainable by me, in accordance with 40 CFR 720.23.

I also agree to permit access to, and the copying of records by a duly authorized representative of the EPA Administrator in accordance with the Toxic Substances Control Act and any regulations issued thereunder, to document any information reported in this form.

Signature of authorized official

Date

CONFIDENTIALITY CERTIFICATION

I hereby certify to the truth and accuracy of the following four statements concerning all information which is claimed confidential.

- **a.** My company has taken measures to protect the confidentiality of the information, and it will continue to take these measures;
- **b.** The information is not, and has not been, reasonably obtainable by other persons (other than governmental bodies) by using legitimate means (other than discovery based on a showing of special need in a judicial or quasi-judicial proceeding) without the company's consent;
- **c.** The information is not publicly available elsewhere; and
- **d.** Disclosure of the information claimed confidential would cause substantial harm to my company's competitive position.

Signature of authorized official

Date

EPA Form 7710-25 (9-79)

Part I – GENERAL INFORMATION

Section A – MANUFACTURER IDENTIFICATION

If you claim Manufacturer's identity confidential, mark (X) the box at the right. → ☐
The answers to items 1, 2, and 3 will be included in this claim.

If you claim the answers to items 4 or 5 confidential, place the letter(s) A–F in the box which indicates the basis of your claim and answer the linkage questions in appendix A, section II, for categories A–E.

Confidential code

1. Person Filing Notice

Name of authorized official — Title

Organization

Mailing address *(Number and street)*

City, State, ZIP code

2. Technical Contact

Name — Title

Mailing address *(Number and street)*

City, State, ZIP code — Telephone — Area code — Number

3. Parent Company

Name

Mailing address *(Number and street)*

City, State, ZIP code

4. Enter the intended date of commencement of manufacture for commercial purposes. — Month — Year

If the intended date of commencement of manufacture is more than 3 years after the date of this notice, submit evidence of intent to manufacture in accordance with 40 CFR 720.20(h).

☐ *Mark this box if you attach evidence.*

5. If you have had a Prenotice Communication (PC) concerning this notice and EPA assigned a PC number to this notice, enter PC Number → ______ *Mark (X) if none* → ☐

CONTINUE WITH SECTION B ON PAGE 3

Section B – CHEMICAL IDENTITY

If you claim Chemical Identity confidential, mark (X) the box at the right. The answers to items 1, 2, and 3 will be included in this claim. → ☐

If you claim Chemical Identity confidential, is this claim limited to the period prior to manufacture? 1 ☐ Yes 2 ☐ No

If you claim the answer to item 4 confidential, place the letter(s) A–F in the box which indicates the basis of your claim and answer the linkage questions in appendix A, section II, for categories A–E.

Complete either 1, 2, or 3 as appropriate. Complete 4.

		Confidential code
1. Class 1 Chemical Substance (other than polymers)	a. CAS Registry No. (if known)	
	b. Specific chemical name	
	c. Molecular formula	
	d. Synonyms	
	e. Trademarks	
	f. Structural diagram	
	☐ *Mark this box if you attach a continuation sheet.*	
2. Class 2 Chemical Substance	a. CAS Registry No. (if known)	
	b. Specific chemical name	
	c. Synonyms	
	d. Trademarks	
	e. List the immediate precursor substance(s) and reactants with their respective CAS Registry Number(s) and describe the nature of the reaction. Also provide a partial or incomplete chemical structure diagram (where appropriate). Indicate the range of composition.	
	☐ *Mark this box if you attach a continuation sheet.*	

3. Polymers

a. (1) Provide the specific chemical names and the CAS Registry Number of those monomers and other reactants used in the manufacture of the polymer. (2) Mark (X) the identity column if you wish monomers used at two percent (by weight) or less to be listed as part of the polymer description on the inventory. (3) Provide the intended range of composition of the polymer in terms of monomer percent (by weight). If your notice is for any copolymer of the listed monomers, enter "any" under Range of Composition. (4) For each monomer, indicate the maximum amount (weight percent) that may be present as a residual in the polymer as distributed in commerce.

Monomers and CAS Registry No. (1)	Identity *Mark (X)* (2)	Range of composition (3)	Maximum amount (weight percent) (4)	Confidential code (5)
			%	
			%	
			%	
			%	

b. Indicate the minimum average molecular weight or the minimum degree of polymerization of the polymeric compositions to which this notice applies.

☐ *Mark this box if you attach a continuation sheet.*

4. Impurities

(a) List each impurity, including CAS Registry Number, which may reasonably be anticipated to be present in the chemical substance as it will be manufactured for commercial purposes. (b) Estimate the maximum percent (by weight) of each impurity. Base your answer on information developed during R & D activities, your knowledge of manufacturing process chemistry and anticipated quality control operations. (c) Mark (X) if the concentration of an impurity will be specifically controlled because of your concern about potential adverse health or environmental effects. (d) Estimate the maximum total percent (by weight) of the impurities that may be present.

Impurity and CAS Registry number (a)	Maximum percent present (b)	*Mark if to be specifically controlled* (c)	Confidential code
	%		
	%		
	%		
	%		
	%		
	%		
	%		
	%		
	%		
d. Total percent ⟶	%		

☐ *Mark this box if you attach a continuation sheet.*

Section C – GENERIC NAMES

Complete this section only if Specific Chemical Identity is claimed confidential.

For instructions on how to develop generic names, see appendix II, 40 CFR 720 (44 FR 2278), Proposed Premanufacture Notification Requirements and Review Procedures.

1. Enter the generic name agreed on by EPA in Prenotice Communication or provide 3 generic names.

Section D – PRODUCTION AND MARKETING DATA

If you claim Production Volume confidential, mark (X) the box at the right. → ☐
The answers to item 1 will be included in this claim.

1. Estimate the minimum and maximum annual production volume for the first three years of production. Include in your estimates production by others with whom you have contracted to manufacture the new chemical substance.

Production year (1)	Production (Kg/yr) Minimum (2)	Production (Kg/yr) Maximum (3)	Confidential code
a. First year			
b. Second year			
c. Third year			

2. **Category of use**

If you claim Use Data confidential, mark (X) the box at the right. → ☐
The answers to item 2 will be included in the claim.

a. List the category(ies) of use on which you have based your production estimates. (Example: solvent used in automotive paint.) List partial information if complete information is not known. (Example: solvent.) Mark (X) the categories of use as site limited, industrial, commercial, or consumer. Estimate the percent of total production for the first 3 years devoted to each category of use.

Category of use (1)	Production percent (2)	*Mark (X) appropriate column(s)* Site limited (3)	Industrial (4)	Commercial (5)	Consumer (6)	Confidential code
	%					
	%					
	%					

☐ *Mark this box if you attach a continuation sheet.*

b. List any other category(ies) of use that you have actively explored

☐ *Mark this box if you attach a continuation sheet.*

c. Do you intend or expect the new chemical substance to be used to treat drinking water supplies or to be used in products (e.g., paints or coatings) that will come in contact with drinking water? 1 ☐ Yes 2 ☐ No 3 ☐ Don't know

NOTE – If you claim the answers to items 3 or 5 confidential, place the letter(s) A–F in the box which indicates the basis of your claim and answer the linkage questions in appendix A, section II for categories A–E.

If you claim any item submitted in an attachment confidential, see SPECIAL INSTRUCTIONS, appendix A, section II, part B.

3. Has the chemical substance been manufactured before? 1 ☐ Yes 2 ☐ No 3 ☐ Don't know

4. Hazard warnings — Attach to this notice a copy or reasonable facsimile of any hazard warning statement, label, labeling, marking or instructions, technical data sheet, material safety data sheet, and any other information which will be provided to any person regarding the safe handling, transport, use, disposal, treatment upon accidental exposure, or the formulation, construction, or labeling of products containing the new chemical substance.

☐ *Mark this box if you attach a hazard warning.*

5. Enter the number of customers who have either contracted to purchase, submitted a purchase order, or made any other firm commitment to purchase the new chemical substance from you for a category of use unknown to you. Estimate the percentage of your production volume that will be purchased by such customers during the first 3 years of production.

Number of customers	Percentage production volume	Confidential code
	%	

Section E – TRANSPORT

Complete this section if you intend to ship the new chemical substance from its site of manufacture.

If you claim the answers to items 1 or 2 confidential, place the letter(s) (A–F) in the box which indicates the basis of your claim and answer the linkage questions in appendix A, section II for categories A–E.

1. Enter the proper DOT shipping name and hazard class of the new chemical substance (if applicable).

	Confidential code
a. Shipping name	
b. Hazard class	

2. Mark (X) the mode(s) of transport which you believe will be used for the new chemical substance.

1 ☐ Truck
2 ☐ Railcar
3 ☐ Barge, vessel
4 ☐ Pipeline
5 ☐ Plane
6 ☐ Other – *Specify*

Section F – RISK ASSESSMENT

If you claim any item submitted in an attachment confidential, see SPECIAL INSTRUCTIONS, appendix A, section II, part B.

If you have evaluated the health or environmental risks which may be presented by the manufacture, processing distribution in commerce, use, or disposal of the new chemical substance attach your evaluation.

☐ *Mark this box if you attach a risk assessment.*

Section G – DETECTION METHODS

If you claim the answers to item 1 confidential, place the letter(s) A–F in the box which indicates the basis of your claim and answer the linkage questions in appendix A, section II, for categories A–E.

1. Is an analytical method available to identify and quantify the presence of the new chemical substance –

Identify	Quantify	Confidential code
a. In workplace air? 1 ☐ Yes 2 ☐ No 3 ☐ Don't know	e. In workplace air? 1 ☐ Yes 2 ☐ No 3 ☐ Don't know	
b. In effluent streams? 1 ☐ Yes 2 ☐ No 3 ☐ Don't know	f. In effluent streams? 1 ☐ Yes 2 ☐ No 3 ☐ Don't know	
c. In materials requiring disposal? 1 ☐ Yes 2 ☐ No 3 ☐ Don't know	g. In materials requiring disposal? 1 ☐ Yes 2 ☐ No 3 ☐ Don't know	
d. In end products for which the new substance is an intermediate? 1 ☐ Yes 2 ☐ No 3 ☐ Don't know	h. In end products for which the new substance is an intermediate? 1 ☐ Yes 2 ☐ No 3 ☐ Don't know	

Part II – HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE

Section A – INDUSTRIAL SITES CONTROLLED BY THE SUBMITTER

If you claim Process Information confidential, mark (X) the box at the right. The answer to subsection 2 will be included in this claim. ——→ ☐

If you claim the answers to items in subsections 1, 3, or 4 confidential, enter the letter(s) A–F in the box which indicates the basis of your claim and answer the linkage questions in appendix A, section II for categories A–E. If you claim the answers to items 3.3, 4.3, or 4.4 in subsections 3 or 4, or any items submitted in an attachment confidential, see SPECIAL INSTRUCTIONS, appendix A, section II, part B.

Complete a separate subsection 1 and subsection 2 sheet for each site where you will manufacture, process or use the new chemical substance.

▶ Subsection 1 – PROCESS INFORMATION

			Confiden-tial code
1.1 Identity of site	Name		
	Physical location address *(Number and street)*		
	City, County, State, ZIP code		
1.2 Type of site	1 ☐ Manufacturing 2 ☐ Processing 3 ☐ Use	4 ☐ Continuous 5 ☐ Batch	
1.3 Hours of operation ——→	Days per year	Hours per day	
1.4 Amount manufactured, processed, or used ——→	Minimum Kg/yr.	Maximum Kg/yr.	

▶ Subsection 2 – BLOCK DIAGRAM

2.1 Provide a block diagram identifying the major unit operations and chemical conversions. Also include:

a. For each chemical conversion in the block diagram identify the major chemical reactions and the major side reactions.

b. Provide the approximate mass of all feed materials, byproduct materials, and products which are entering and leaving each major unit operation and chemical conversion. Indicate the method of transfer of these materials and whether the operation is open or closed to the workplace environment.

c. Identify those points in the block diagram from which there will be releases of the new chemical substance or byproduct materials into the air, land, or water environment.

☐ *Mark this box if you attach a continuation sheet.*

▶ Subsection 3 – OCCUPATIONAL EXPOSURE

Complete a separate subsection 3 for each site at which you will manufacture, process, use, or dispose of the new chemical substance. Indicate the anticipated route(s) of exposure to the new chemical substance (e.g., inhalation, ingestion, dermal), the number of employees anticipated to be exposed by each route, and the maximum duration of such exposure (in days per year and hours per day). In the table below, mark (X) A–Average or P–Peak for the concentration levels that are expected to be present in the immediate vicinity of the process equipment. Base your answer on maximum annual production, processing, or use during the first 3 years of manufacture under normal operating conditions with all engineering safeguards in place.

Confidential code

3.1 Identity of site

Name

Physical location address *(Number and street)*

City, County, State, ZIP code

3.2 Occupational Exposure at Industrial Site

Activity (1)	Exposure route(s) (2)	Maximum number exposed (3)	Maximum duration (4)		Concentration (5)								
			Hr./day	Days/yr.	Unit of measure	*Mark (X) appropriate column* A – Average P – Peak							
						0–1		1–10		10–100		> 100	
						A	P	A	P	A	P	A	P
a. Manufacture					1 ☐ ppm 2 ☐ mg/m^3								
b. Processing					1 ☐ ppm 2 ☐ mg/m^3								
c. Use					1 ☐ ppm 2 ☐ mg/m^3								
d. Disposal					1 ☐ ppm 2 ☐ mg/m^3								

3.3 Describe those operations in which workers will be directly exposed to the new chemical substance.

☐ *Mark this box if you attach a continuation sheet.*

3.4 Mark (X) as many of the physical states of the new chemical substance to which workers may be exposed in the workplace.

Confidential code

1 ☐ Solid
2 ☐ Gas
3 ☐ Aerosol
4 ☐ Powder
5 ☐ Mist
6 ☐ Fume
7 ☐ Dust
8 ☐ Liquid
9 ☐ Other – *Specify* ▶

3.5 For each site of manufacture, list any other substances (e.g., byproducts, co-products, feedstocks and intermediates) associated with the manufacture of the new chemical substance that may reasonably be anticipated to be present in the workplace and to which workers may be exposed. Provide the CAS Registry Number.

Substance (1)	CAS Registry Number (2)	Confidential code

☐ *Mark this box if you attach a continuation sheet.*

▶ Subsection 4 – **ENVIRONMENTAL RELEASE AND DISPOSAL**

Complete a separate subsection 4 for each site where you intend to manufacture, process, use or dispose of the new chemical substance.

Confidential code

4.1 Identity of site

Name

Physical location address *(Number and street)*

City, County, State, ZIP code

4.2 Indicate the duration of release into the air and water environment and the annual amount of new chemical substance released to the air, water, and land. Mark (X) the disposition of the water discharge and estimate the effluent flow rate from the site. Enter the name of the POTW or receiving water body. Base your answer on maximum annual production during the first 3 years of manufacture under normal operating conditions.

Media	Duration of release		Amount of new chemical substance released (Kg/yr.)					
(1)	Hrs./day (2)	Days/yr. (3)	Less than 10 (4)	10–100 (5)	100–1000 (6)	1000–10,000 (7)	More than 10,000 (8)	
a. Air								
b. Land								
c. Water								

1 ☐ POTW (Publicly Owned Treatment Works)
2 ☐ Navigable waterway
3 ☐ Other

Enter name ▶

d. Effluent stream flow rate ——▶ Gallons per day

4.3 For each release point indicated in the block diagram, characterize the composition of the release materials.

☐ *Mark this box if you attach a continuation sheet.*

4.4 Describe pollution control equipment and disposal operations (e.g., scrubber, baghouse, landfill, incinerator, activated sludge, carbon absorption, etc.) used to treat individual or combined releases indicated in the block diagram(s) of manufacturing, processing, and use operations.

☐ *Mark this box if you attach a continuation sheet.*

Section B – INDUSTRIAL SITES CONTROLLED BY OTHERS

Complete this section using your own forecasts, any information already obtained from other persons who may process, use, dispose of, or manufacture (under contract) the new chemical substance or any other information that is reasonably ascertainable. Complete a separate subsection 1 and subsection 2 for each site where you expect other persons to manufacture (under contract), process, use, or dispose of the new chemical substance.

If you claim the answers to the items in subsections 1, 3, or 4 confidential, enter the letter(s) A–F in the box which indicates the basis of your claim and answer the linkage questions in appendix A, section II, for categories A–E.

If you claim the answers to items in subsection 2, or item 3.3 in subsection 3 confidential, see SPECIAL INSTRUCTIONS in appendix A, section II, part B.

▶ Subsection 1 – PROCESS INFORMATION

		Confidential code
1.1 Identity of site (Optional)	Name	
	Physical location address (Number and street)	▨
	City, State, ZIP code	▨
	County	▨

▶ Subsection 2 – PROCESS DESCRIPTION

Briefly describe processing, use, or manufacturing operations conducted by others.

☐ *Mark this box if you attach a continuation sheet.*

▶ Subsection 3 – OCCUPATIONAL EXPOSURE

Complete a separate subsection 3 for each industrial site where you expect other persons to process, use, dispose of, or manufacture the new chemical substance. Indicate the anticipated routes of exposure to the substance (e.g., inhalation, ingestion, dermal), the number of employees anticipated to be exposed by each route, and the maximum duration of such exposure (in days per year and hours per day). In the table below, mark (X) A—Average or P—Peak for the concentration levels that are expected to be present in the immediate vicinity of the process equipment. Base your answer on the maximum amount anticipated to be manufactured, processed, used, or disposed during the first 3 years of operation under normal conditions with all engineering safeguards in place.

Confidential code

3.1 Identity of site (optional)

Name

Physical location address *(Number and street)*

City, State, ZIP code

County

3.2 Occupational Exposure at Industrial Site

Activity (1)	Exposure route(s) (2)	Maximum number exposed (3)	Maximum duration (4)		Concentration (5)									
					Unit of measure	*Mark (X) appropriate column* A – Average P – Peak								
						0–1		1–10		10–100		> 100		
			Hrs./day	Days/yr.		A	P	A	P	A	P	A	P	
a. Manufacture					1 ☐ ppm 2 ☐ mg/m³									
b. Processing					1 ☐ ppm 2 ☐ mg/m³									
c. Use					1 ☐ ppm 2 ☐ mg/m³									
d. Disposal					1 ☐ ppm 2 ☐ mg/m³									

3.3 Describe those activities in which workers will be directly exposed to the new chemical substance.

☐ *Mark this box if you attach a continuation sheet.*

3.4 Mark (X) as many of the physical states of the new chemical substance to which workers may be exposed in the workplace.

Confidential code

1 ☐ Solid
2 ☐ Gas
3 ☐ Aerosol
4 ☐ Powder
5 ☐ Mist
6 ☐ Fume
7 ☐ Dust
8 ☐ Liquid
9 ☐ Other – *Specify*

▶ Subsection 4 – ENVIRONMENTAL RELEASE AND DISPOSAL

Complete a separate subsection 4 for each site where other persons intend to manufacture, (under contract) process, use, or dispose of, the new chemical substance.

Confidential code

4.1 Identity of site (Optional)

Name

Physical location address *(Number and street)*

City, State, ZIP code

County

4.2 Indicate the duration of release into the air and water environment and the annual amount of new chemical substance released to the air, water, and land. Mark (X) the disposition of the water discharge and estimate the effluent flow rate from the site. Enter the name of the POTW or receiving water body. Base your answer on maximum annual production during the first 3 years of manufacture under normal operating conditions.

Media (1)	Duration of release		Amount of new chemical substance released (Kg/yr.)					
	Hrs./day (2)	Days/yr. (3)	Less than 10 (4)	10–100 (5)	100–1000 (6)	1000–10,000 (7)	More than 10,000 (8)	
a. Air								
b. Land								
c. Water								

1 ☐ POTW (Publicly Owned Treatment Works)
2 ☐ Navigable waterway
3 ☐ Other

Enter name

d. Effluent stream flow rate → Gallons per day

4.3 (1) List any byproduct materials containing the new chemical substance that are generated during manufacturing, use, and processing operations and which are disposed of (e.g., landfill, incineration, or other physical/chemical treatment). Water effluent and air emission streams should not be listed here. Estimates of release of the new chemical substance contained in such streams are required to be reported in item 4.2. (2) Indicate the method of disposal. (3) Estimate the amount of each material generated (Kg/Kg of the new chemical substance), and (4) estimate the percent (by weight) of the new chemical substance.

Material requiring disposal (1)	Anticipated method of disposal (2)	Amount (Kg/Kg) (3)	Percent of new chemical substance (4)	Confidential code

☐ *Mark this box if you attach a continuation sheet.*

Section C – CONSUMER AND COMMERCIAL USER EXPOSURE

Complete this section for all consumer and commercial categories of use which involve use of a product that intentionally contains the new chemical substance. *Provide the information based on your own forecasts, information already obtained from other persons, or any other information that is reasonably ascertainable.*

If you claim the answers to item 1 confidential, enter letter(s) A–F in the box which indicates the basis of your claim and answer the linkage questions in appendix A, section II, for categories A–E.

If you claim the answers to items 2, 3, or 4 confidential, see SPECIAL INSTRUCTIONS, appendix A, section II, part B.

1. Complete the table below. For each consumer and commercial use category reported in section D, item 2, mark (X) if the product will be manufactured by the submitter or by other persons. Indicate the maximum number of consumers or commercial users expected to be exposed, the expected routes of human exposure and the frequency of exposure.

Category of use from part II, section D (1)	Use category (2)		Manufactured by – (3)		Exposure route(s) (4)	Maximum number exposed (5)	Frequency of exposure (6)				Confidential code
	Consumer	Commercial	Submitter	Other			Daily	Weekly	Monthly	Yearly	

2. Attach any estimates that have been developed of potential exposure levels for each category of use.

☐ *Mark this box if you attach any estimates.*

3. For each product containing the new chemical substance, explain any aspect of its construction or formulation which you believe will limit the potential for exposure to the new chemical substance. For mixtures, indicate the maximum percent by weight of the chemical substance in the product.

☐ *Mark this box if you attach a continuation sheet.*

4. Identify any byproducts which are formed as a result of each category of use described in this section.

☐ *Mark this box if you attach a continuation sheet.*

Part III – LIST OF ATTACHMENTS

Under section 5(d)(1)(B) and (C) of TSCA and 40 CFR 720.23, a manufacturer must submit all test data in his possession and control, and a description of any other data that are known to or reasonably ascertainable by him/her concerning the effect of manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance on health or the environment. The regulations specify which data must be submitted with the notice and which data may be referenced by literature citations. Using the categories provided, identify (1) attachments containing test data, descriptions of data, or literature citations in accordance with 720.23; (2) other attachments required to be submitted with this notice; (3) confidentiality substantiations and (4) attachments which contain information voluntarily submitted. All attachments should be clearly identified and numbered.

To assert and substantiate a claim of confidentiality for any information included in the following attachments, follow the instructions in Appendix A, section II, part B. Note – Special directions for test data or other "Health and Safety" studies included in section III, part C.

The instructions provide that you must also submit a "sanitized" copy of the attachment with all information that you are claiming confidential deleted. EPA will place this copy in the public docket.

	Attachment name	Attachment number
a. Physical and chemical properties data		
b. Health and environmental effects data		

	Part	Section/Subsection	Item	
c. Notice attachments				
d. Confidentiality attachments				
e. Voluntary attachments				

☐ *Mark this box if you attach a continuation sheet.*

Part IV – FEDERAL REGISTER NOTICE

Information provided in this part will be published in the Federal Register in accordance with section 5(d)(2) of TSCA. Do not enter any information in this part for which you have asserted a claim of confidentiality.

Section A – CHEMICAL IDENTITY

Enter the specific chemical name of the substance if it is not claimed confidential. If the chemical identity is claimed confidential, enter the name agreed to by EPA in Prenotice Communication or EPA will enter one of the three proposed generic names in part I, section C.

Section B – MANUFACTURER IDENTIFICATION

Enter the legal title of the organization filing this notice if it is not claimed confidential. If the legal title of the organization is claimed confidential, provide a description of the organization in accordance with section II, Appendix A, Instructions for Asserting and Substantiating Claims of Confidentiality.

Section C – USE DATA

1. If use data were not claimed confidential in section D, list the category(ies) of use that you reported in section D, item 2a. Mark (X) if the use category(ies) is site limited, industrial, commercial, or consumer.

Category of use (1)	Mark (X) appropriate box			
	Site limited (2)	Industrial (3)	Commercial (4)	Consumer (5)

2. If use data were claimed confidential, provide a description of the category of use(s) of the chemical substance in accordance with section II, Appendix A, Instructions for Asserting and Substantiating Confidentiality. This description should be as specific as possible without revealing confidential information.

Section D – TEST DATA

List all test data concerning health and environmental effects of the manufacture, processing, distribution, in commerce, use, or disposal of the new chemical substance that are being submitted, described, or cited as part of this notice. Provide a brief abstract of all test data on the new chemical substance that are submitted in accordance with 720.23(a) and 720.20(j). If physical-chemical properties are claimed confidential, provide a generic description of these properties in accordance with section III, Appendix A, Instructions for Asserting and Substantiating Claims of Confidentiality.

☐ *Mark this box if you attach a continuation sheet.*

PREMANUFACTURE NOTICE

CERTIFICATION STATEMENT: It is hereby certified that, to the best of its knowledge and belief: (1) the submitter of this form intends to manufacture for a commercial purpose the chemical substance for which this notice is submitted, other than in small quantities for research and development, and that the substance is not excluded from premanufacture notification under Section 5 of the Toxic Substance Control Act (TSCA); (2) all information entered on this form is complete and truthful as of the date of submittal; (3) the form contains all information described in Sections 8(a)(2)(A)-(D) and (F)-(G) of TSCA insofar as it is known to or reasonably ascertainable by the submitter, as required by Section 5(d)(1)(A) of TSCA; and (4) submitted with this form are all test data in the possession or control of the submitter which are related to the effect of any manufacture, processing, distribution in commerce, use or disposal of the new chemical substance or any article containing such substance on health or the environment, and a description of any other data concerning the effects of the substance on health or the environment that are known to or reasonably ascertainable by the submitter, as required by Sections 5(d)(1)(B) and (C) of TSCA.

____
(Name of Submitter)

By: ______________________________
(Signature of Authorized Official)

____
(Date)

When completed, send this notice to:

Document Control Officer
Office of Toxic Substances
TS-793
U.S.E.P.A.
401 M Street, S.W.
Washington, D.C. 20460

CONFIDENTIALITY INSTRUCTIONS: If a claim of confidentiality is asserted for any data or information contained in this notice, a check must be placed in the box in the left hand margin immediately adjacent to the data or information entry. If a claim of confidentiality is not asserted on this form at the time of submission of the information, EPA may make the information public without further notice. Claims of confidentiality must be made and substantiated in accordance with Section 14 of TSCA and EPA's rules (40 C.F.R. § ___).

FOR EPA USE ONLY
Date of receipt ________________

GENERAL INSTRUCTIONS

These instructions are intended to assist the submitter of a premanufacture notice in the use of the Premanufacture Notice Form.

The Premanufacture Notice Form consists of the four parts listed below. Each part consists of two or more sections.

Part I - General Information

Part II - Risk Assessment Data

Part III - Optional Risk Analysis Information

Part IV - Optional Additional Information On Workplace Exposure and Environmental Release

All sections of Parts I and II must be completed by the submitter. Section 5 of TSCA does not require the submission of Parts III or IV. These parts, or selected sections, may be completed at the discretion of the submitter.

In completing Parts I and II, the submitter must provide EPA with all test data in its possession or control which are related to the effect of any manufacture, processing, distribution in commerce, use or disposal of the chemical substance or any article containing it on health or the environment and a description of any other data concerning the effects of the substance on health or the environment that are known to or reasonably ascertainable by the submitter. In addition, it must provide all of the other information and data requested that are known to or reasonably ascertainable by it. Thus, it must answer all questions to the best of its ability, including reasonable estimates where it does not know with factual certainty the answers to particular questions. In cases where the submitter cannot provide a reasonable estimate (i.e., the information is unknown and is not reasonably ascertainable), it should enter NA (not available). Information is "reasonably ascertainable" if it is information which a business in the submitter's position would usually possess in the normal course of preparing to manufacture a new chemical substance for commercial purposes, taking into account customary business practice in light of all relevant economic and safety considerations relating to the new chemical substance.

PART I

GENERAL INFORMATION

All data requested in this Part must be provided insofar as they are known to or reasonably ascertainable by the submitter. In cases where the requested data are unknown and not reasonably ascertainable, enter NA (not available).

Section A. Submitter Identification

1. Person Filing Notice

[ ] Legal Title of Organization______________________

[ ] Name of Authorized Official______________________

[ ] Title______________________

[ ] Mailing Address______________________

____

2. Technical Contact

[ ] Name______________________

[ ] Title______________________

[ ] Mailing Address______________________

____

[ ] Telephone Number______________________

Section B. Chemical Identity

Complete either 1, 2, or 3 as appropriate. Complete 4. If chemical identity is claimed confidential also complete 5.

1. Class I chemical substance (40 C.F.R. § ___) (other than polymers)

[ ] a. CAS Registry No. (if known)______________________

[ ] b. Specific Chemical Name______________________

[ ] c. Molecular Formula______________________

[ ] d. Synonyms______________________

[ ] e. Trademarks______________________

[ ] Structural Diagram

2. Class II chemical substance (40 C.F.R. § ___).

[ ] a. CAS Registry No. (if known)________________

____

[ ] b. Specific Chemical Name________________

____

[ ] c. Synonyms________________

[ ] d. Trademarks________________

[ ] e. List the immediate precursor substance(s) and/or reactants with their respective CAS Registry Number(s) and the nature of the reaction. Also provide a partial or incomplete chemical structure diagram (where appropriate). Indicate the range of composition.

3. Polymers

(1) Provide the specific chemical name and the CAS Registry Number of those monomers and reactants used at greater than two percent (by weight) in the manufacture of the polymer. Monomers used at two percent (by weight) or less need not be listed as part of the polymer description. (2) Provide the intended range of composition of the polymer in terms of monomer percent (by weight). Calculate the percent based on the composition of the polymer formed. If the notice is for any copolymer of the listed monomers, enter "any" under Range of Composition. (3) For each monomer, indicate the maximum amount (in percent weight) that may be present as a residual in the polymer as distributed in commerce.

	(1) Monomers and CAS Registry No.	(2) Range of Composition	(3) Maximum Residual (Weight Percent)
[ ]			
[ ]			
[ ]			

4. Impurities

Estimate the purity (by weight) of the chemical substance as it will be manufactured for commercial purposes.

Total Percent ____________________

List the identities and estimate the maximum percent (by weight) of those identified impurities which may reasonably be anticipated to be present in the chemical substance as it will be manufactured for commercial purposes. Base the answer on information developed during R&D activities, knowledge of manufacturing process chemistry, and anticipated quality control operations.

	Identity	Maximum Percent
[ ]		
[ ]		
[ ]		

5. Chemical Identity Claimed Confidential

If claimed for a period prior to or following commencement of manufacture:

Proposed Generic Name: ____________________

Is this claim limited to the period prior to manufacture?

☐ Yes ☐ No

Substantiation and other materials required to be submitted with a claim of confidentiality must be attached.

Section C. Production and Categories of Use Information

1. Estimate total production volume for the first three years of manufacture. (Use the ranges set forth at 40 C.F.R. § ___.) Include in your estimates production by others with whom you have contracted to manufacture the chemical substance.

		Production
[ ]	a. First Calendar Year	________
[ ]	b. Second Calendar Year	________
[ ]	c. Third Calendar Year	________

2. Production Estimates for Categories and Proposed Categories of Use.

List the categories and proposed categories of use (e.g., captive intermediate) for the substance and estimate the percent of the maximum anticipated annual production volume which will be devoted to each category and proposed category of use during the first three calendar years of production.

	Category of Use	Percent of Production
[ ]	________	________
[ ]	________	________
[ ]	________	________
[ ]	________	________

Section D. Federal Register Notice

Information provided in this section will be published in the Federal Register in accordance with Section 5(d)(2) of TSCA. Separate sections are provided for presentation of data related to confidential information where appropriate. Do not enter any information in this section which you consider confidential.

1. Generic class of substance or, if you consent to its disclosure in the Federal Register, its chemical identity.

___

2. Use information.

List each non-confidential category and proposed category of use for the chemical substance.

___

___

___

___

3. If any data relating to the chemical substance are being submitted pursuant to Section 5(b) or Section 4 of TSCA, describe the nature of the tests performed and any data developed.

___

___

___

___

___

___

Section E.

Provide a list of all attachments which are submitted with this form.

PART II

RISK ASSESSMENT DATA

Section A. Chemical Properties, Environmental Fate Characteristics, and Human and Ecological Effects Data.

Under Sections 5(d)(1)(B) and (C) of TSCA, a submitter must submit all test data in its possession and control relating to the effects of any manufacture, processing, distribution in commerce, use or disposal of the chemical substance or any article containing it on health or the environment. It must also describe any other data concerning the effects of the substance on health or the environment that are known to or reasonably ascertainable by the submitter. Using Table 1, identify the test data relating to physical and chemical properties and health and environmental effects for which you have submitted: (1) data, (2) a description of data, and/or (3) a literature citation. You may wish to provide additional information or explanation to EPA. Section A of Part III is an optional section which provides a format for the presentation of such information.

Table 1

CONFIDENTIALITY: The information that is required to be entered in this table is limited to an identification of the physical/chemical properties and health and environmental effects for which test data or a description of data have been submitted with this notice. If a claim of confidentiality is asserted for any of these data, the attached document(s) which contain(s) the data must be marked "confidential."

1. Test Data on Physical/Chemical Properties.

(1) data submitted
(2) description submitted
(3) literature citation

	Type of Test Data	(1)	(2)	(3)
[ ]	1. ____________________	[ ]	[ ]	[ ]
[ ]	2. ____________________	[ ]	[ ]	[ ]
[ ]	3. ____________________	[ ]	[ ]	[ ]
[ ]	4. ____________________	[ ]	[ ]	[ ]

2. Test Data on Health and Environmental Effects.

(1) data submitted
(2) description submitted
(3) literature citation

	Nature of Test Data	(1)	(2)	(3)
[ ]	1. ________________	[ ]	[ ]	[ ]
[ ]	2. ________________	[ ]	[ ]	[ ]
[ ]	3. ________________	[ ]	[ ]	[ ]
[ ]	4. ________________	[ ]	[ ]	[ ]

Section B. Occupational Exposure, Disposal, By-Products

All the data requested in this Section must be provided insofar as they are known to or reasonably ascertainable by the submitter. In cases where the requested data are unknown and not reasonably ascertainable enter NA (not available).

1. Industrial Sites Controlled by the Submitter.

a. Occupational Exposure. For each site at which you will manufacture, process, use or dispose of the chemical substance, indicate the anticipated route of exposure to the substance (e.g., inhalation, ingestion, dermal), the number of employees anticipated to be exposed by each route, and the maximum duration of such exposure (in days per year and hours per day). Base your answer on maximum annual production, processing, or use during the first three years of manufacture under normal operating conditions with all safeguards in place. (Use the ranges set forth at 40 C.F.R. § ____.) If more than one site is involved, attach supplemental forms.

Identity of Site	Route(s)	No. of Exposed Employees	Maximum Duration of Exposure
____________	a. ________	__________	__________
	b. ________	__________	__________
	c. ________	__________	__________

b. Disposal of Chemical Substance. For each site at which you will manufacture, process, use, or dispose of the chemical substance, identify its anticipated methods of disposal, if any, including release into the environment. Indicate whether these methods of disposal will occur incidental to the manufacture, processing or use of the substance or will follow its end use. Include only forms of disposal which are deliberate or planned. Fugitive or inadvertant release of the substance into the environment should not be listed. Where there will be no disposal of the chemical substance at the site, check "none." For each form of disposal which you identify, indicate whether it will result in "minimal" release of the substance into the environment. "Minimal" release is release which, taking into account all relevant factors, is too small to have a material effect on the environment. You may explain the basis for this conclusion in Part III of this form if you wish. If more than one site is involved, attach supplemental forms.

	Identity of Site	Method of Disposal (Check)		Minimal (Check)	End Use (Check)	Inci dent (Che
[ ]		Air				
[ ]		Water				
[ ]		Land				
[ ]		Destruction				
[ ]		Other				
[ ]		None				

c. By-Products. For each site at which you will manufacture the chemical substance, list the CAS Registry Numbers of the identified by-products that reasonably may be anticipated to result from the manufacture of the chemical substance. If more than one site is involved, attach supplement forms.

	Identity of Site	By-Product (CAS No.)	
[ ]		a.	
[ ]		b.	
[ ]		c.	
[ ]		d.	

2. Industrial Sites Not Controlled by Submitter.

a. Workplace Exposure.

Using any information already obtained from other persons who may process or use the substance or from your own forecasts and any other information that is reasonably ascertainable, indicate the anticipated employee exposure to the chemical substance at industrial sites that you do not control but where you expect it will be processed, used or disposed of. For each site, indicate the anticipated route of exposure to the substance (e.g., inhalation, ingestion, dermal), the number of employees anticipated to be exposed by each route, and the maximum duration of such exposure (in days per year and hours per day). Base your answer on maximum annual production, processing, or use during the first three years of manufacture under normal operating conditions with all safeguards in place. (Use the ranges set forth at 40 C.F.R. § ___.) If more than one site is involved, you may provide one answer for all sites combined or use separate forms for each site.

	Identity of Site	Route(s)	No. of Exposed Employees	Maximum Duration of Exposure
[ ]	____________	a. ________	________	________
[ ]		b. ________	________	________
[ ]		c. ________	________	________

b. Disposal of Chemical Substance.

Using any information already obtained from other persons who may process or use the chemical substance or from your own forecasts and any other information that is reasonably ascertainable, identify the anticipated methods of the chemical substance's disposal, if any, including release into the environment, at industrial sites which you do not control but where you expect the substance will be processed, used or disposed of. Indicate whether these methods of disposal will occur incidental to its manufacture, processing or use or will follow its end use. Include only forms of disposal which are deliberate or planned. Fugitive or inadvertant release of the substance into the environment should not be listed. Where there will be no disposal of the chemical substance at the site, check "none." For each form of disposal which you identify, indicate whether it will result in "minimal" release of the substance into the environment. "Minimal" release is release which, taking into account all relevant factors, is too small to have a material effect on the environment. You may explain the basis for this conclusion in Part III of this form if you wish. If more than one site is involved, you may provide one answer for all sites combined or use separate forms for each site.

	Identity of Site	Method of Disposal (Check)		Minimal (Check)	End Use (Check)	Inci dent (Che
[ ]	________	Air	____	____	____	____
[ ]		Water	____	____	____	____
[ ]		Land	____	____	____	____
[ ]		Destruction	____	____	____	____
[ ]		Other	____	____	____	____
[ ]		None	____			

DRAFT

EPA United States Environmental Protection Agency APR 29 1982

PREMANUFACTURE NOTICE

AGENCY USE ONLY

Date of receipt

DRAFT

When completed send this form to:

DOCUMENT CONTROL OFFICER
OFFICE OF TOXIC SUBSTANCES, TS-793
U.S. E.P.A.
401 M STREET, SW
WASHINGTON, D.C. 20460

Enter the total number of pages in the Premanufacture Notice

Document control number

EPA case number

GENERAL INSTRUCTIONS

This Premanufacture Notice form is divided into four parts. Parts I, II, and III are mandatory. You must provide all information requested to the extent that it is known to or reasonable ascertainable by you. Make reasonable estimates if you do not have actual data. If you do not know or cannot ascertain the information, enter "NK" (not known or reasonably ascertainable). The parts are:

I. GENERAL INFORMATION

You must provide the chemical identity of the substance, even if you claim the identity as confidential. You may authorize another person to report the identity for you, but your submission will not be complete and review will not begin until EPA receives this information.

II. HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE

You may need additional copies of part II, sections A and B if there are several manufacturing, processing, or industrial use sites, or if there are several operations at an individual site. You may obtain additional sections of these from the Office of Toxic Substances Industry Assistance Office.

III. LIST OF ATTACHMENTS

You should attach additional sheets if you do not have enough space on the form to answer a question fully. In part III, list these attachments and any test data, optional data, and confidentiality materials you include in the Notice.

IV. OPTIONAL INFORMATION

You may include any information you think EPA should consider in evaluating the new substance. This section suggests categories of optional information.

Before you complete this form you should read the "Instructions Manual for Premanufacture Notification."

ASSERTING AND SUBSTANTIATING CONFIDENTIALITY CLAIMS

You may claim any information in this notice as confidential. For instructions on claiming information as confidential and substantiating those claims, read part II of the **Instructions Manual.**

You must assign each of your confidentiality claims to one of the seven categories listed below. Mark (X) the box next to the categories you have claimed in the form as confidential.

☐ A. SUBMITTER IDENTITY
☐ B. CHEMICAL IDENTITY
☐ C. PRODUCTION VOLUME
☐ D. USE INFORMATION
☐ E. PROCESS INFORMATION
☐ F. PORTIONS OF A MIXTURE
☐ G. OTHER INFORMATION

TEST DATA AND OTHER DATA

You are required to submit all test data in your possession or control and to provide a description of all other data known or reasonably ascertainable if these data are related to the health and environmental effects of the manufacture, processing, distribution in commerce, use, and disposal of the new chemical substance. Test data include data concerning the new chemical substance, and any impurity, byproduct, coproduct, degradation product, unintended reaction product, or other substance or mixture related to the manufacture, processing, distribution in commerce, use, or disposal of the new substance. Test data also include data analyses and risk assessment.

Following are examples of test data. The **Instructions Manual** provides additional examples.

- Environmental fate data
    - Spectra (UV and visible)
    - Density of liquids and solids
    - Water solubility
    - Melting point/melting range
    - Boiling point/boiling range
    - Vapor pressure
    - Partition coefficient, n-octanol/water
    - Volatilization from water and soil
    - Biodegradation
    - Hydrolysis (as a function of pH)
    - Chemical oxidation
    - Photochemical degradation
    - Adsorption/desorption to soil types
    - Dissociation constant
- Health effects data
    - Mutagenicity
    - Carcinogenicity
    - Teratogenicity
    - Acute toxicity
    - Repeated dose toxicity
    - Metabolism studies
    - Sensitization
    - Irritation
- Environmental effects data
    - Microbial and algal toxicity
    - Terrestrial vascular plant toxicity (e.g., seed germination studies, growth inhibition)
    - Acute and chronic toxicity to animals (e.g., fish, birds, mammals, invertebrates)
- Risk assessments
- Structure/activity relationships

EPA Form 7710-25 (4-5-82)

DRAFT

CERTIFICATIONS

PR 29

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GENERAL CERTIFICATION

I certify that to the best of my knowledge and belief:

1. The company named in part I, section A, subsection 1, of this notice form intends to manufacture or import for a commercial purpose, other than in small quantities for research and development, the substance identified in part I, section B.
2. The substance identified is not exempt from premanufacture notification.
3. All information provided in this notice is complete and truthful as of the date of submission.
4. I am submitting with this notice all test data in my possession or control and a description of any other data known to or reasonably ascertainable by me if these data are related to the effects of the substance on health and the environment.

I will allow an authorized representative of the EPA Administrator to examine and copy records in accordance with the Toxic Substances Control Act to document any information in this notice.

Confidential code

Signature of authorized official

Date

CONFIDENTIALITY CERTIFICATION

For all information claimed as confidential, I certify that to the best of my knowledge and belief:

1. The company named in part I, section A, subsection 1, protects the confidentiality of the information and will continue to protect it.
2. The information has not been reasonably ascertainable by other persons (excluding governmental bodies) using legitimate means (excluding discovery based on a showing of special need in a judicial or quasi judicial proceeding) without the company's consent.
3. The information is not publicly available.
4. Disclosure of the information would substantially harm my company's competitive position.

Signature of authorized official

Date

Part I – GENERAL INFORMATION

Section A – SUBMITTER IDENTIFICATION

If you claim the category "Submitter Identity" as confidential, mark (X) the box at the right. → ☐

You do not have to answer linkage questions for the certification signatures and for subsections 1, 2, and 3 if you make this claim. If you want to claim these subsections individually, do not mark the box.

Place the letter(s) A–G in the confidential code box next to any subsection you claim as confidential to indicate the basis of your claim. Answer the linkage questions in the **Instructions Manual** for categories A–F.

Confidential code

1. Person submitting notice

Name of authorized official

Title

Organization

Mailing address *(number and street)*

City, State, ZIP code

2. Technical contact

Name

Title

Mailing address *(number and street)*

City, State, ZIP code

Telephone | Area code | Number

3. Have you submitted a test marketing exemption (TME) application for the chemical substance covered by this notice? ☐ Yes ☐ No

4. Have you submitted a bona fide request for the chemical substance covered by this notice? ☐ Yes ☐ No

FORM EPA-7710-25 (4-6-82)

Part I – GENERAL INFORMATION

Section B – CHEMICAL IDENTITY

If you claim the category "Chemical identity" as confidential, mark (X) the box at the right. → ☐

You do not have to answer linkage questions for items in subsections 1 and 2 if you make this claim. If you want to claim items in these subsections individually, do not mark this box.

If you claim chemical identity confidential, is **this claim limited to the period before manufacture?** → 1 ☐ Yes 2 ☐ No

DRAFT

Place the letter(s) A–G in the confidential code box next to any item you claim as confidential to indicate the basis of your claim. Answer the linkage questions in the **Instructions Manual** for categories A–F.

If another person will submit chemical identity information for you, mark (X) the box at the right. → ☐

Complete either item 1 or 2 as appropriate. Complete item 3.

Confidential code

1. Class 1 or 2 chemical substance (for definitions of class 1 and class 2 substances, see the **Instructions Manual**)

Mark (X) class of substance → 1 ☐ Class 1 2 ☐ Class 2

a. Chemical name (preferably CAS or IUPAC nomenclature)

b. Molecular formula and CAS Registry Number (if known)

c. Synonyms for chemical name

d. For a class 1 substance, provide a structural diagram. For a class 2 substance – (1) List the immediate precursor substances with their respective CAS Registry Numbers. (2) Describe the nature of the reaction or process. (3) Indicate the range of composition and the typical composition (where appropriate). (4) Provide a representative structural diagram (where appropriate).

☐ *Mark (X) this box if you attach a continuation sheet.*

FORM EPA-7710-25 (4-5-82)

Part I – GENERAL INFORMATION – Continued

Section B – CHEMICAL IDENTITY – Continued

2. Polymers

a. Indicate the average molecular weight of the polymer. Indicate the method used to determine molecular weight. Provide a range of values if more than one value is anticipated. Characterize the amount of low molecular weight species anticipated. Estimate the weight percent below 1,000 and below 2,000. Describe how you made the estimate. If you intend to manufacture more than one composition of the polymer, provide this information for each composition.

Confidential code

DRAFT

☐ *Mark (X) this box if you attach a continuation sheet.*

b. (1) – Provide chemical names and CAS Registry Numbers of monomers and other reactants used in the manufacture of the polymer.
(2) – Mark (X) the identity column if you want a monomer used at two percent (by weight) or less to be listed as part of the polymer description on the chemical substance inventory.
(3) – Provide the range of composition of the polymer in monomer percent (by weight).
(4) – Indicate the typical or desired composition of the polymer in monomer percent (by weight).
(5) – Indicate the maximum amount of each monomer in percent (by weight) that may be present as a residual in the polymer as distributed in commerce.

If you intend to manufacture more than one composition of the polymer, provide this information for each composition.

Monomer and CAS Registry Number (1)	Identity *Mark (X)* (2)	Range of composition (3)	Typical composition (4)	Maximum residual (5)	
		%	%	%	
		%	%	%	
		%	%	%	
		%	%	%	
		%	%	%	
		%	%	%	
		%	%	%	
		%	%	%	

☐ *Mark (X) this box if you attach a continuation sheet.*

c. Provide a representative structural diagram of the polymer if possible.

☐ *Mark (X) this box if you attach a continuation sheet.*

FORM EPA-7710-25 (4-5-82)

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Part I – GENERAL INFORMATION – Continued

Section B – CHEMICAL IDENTITY – Continued

DRAFT

3. Impurities

(a) – List each impurity, including CAS Registry Number, that may reasonably be anticipated to be present in the chemical substance as it will be manufactured for commercial purpose.
(b) – Estimate the maximum percent (by weight) of each impurity. Base your answer on information developed during R&D activities, your knowledge of manufacturing process chemistry, and anticipated quality control operations.

Impurity and CAS Registry Number (a)	Maximum percent (b)	Confidential code
	%	
	%	
	%	
	%	
	%	
	%	
	%	
	%	

☐ *Mark (X) this box if you attach a continuation sheet.*

4. Trade identification – List trademarks and trade names for the new chemical substance named in subsections 1 or 2.

5. Generic chemical name

If you claim chemical identity as confidential, enter the generic chemical name you developed with EPA in prenotice communication or provide three generic names. If you provide three names, identify the name you prefer. EPA will release only one name for public identification. Read the **Instructions Manual** for guidance on developing generic names.

☐ *Mark (X) this box if you attach a continuation sheet.*

FORM EPA-7710-25 (4-5-82)

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Part I – GENERAL INFORMATION – Continued

Section C – PRODUCTION, IMPORT, EXPORT, AND USE DATA

If you claim the category "Production Volume" as confidential, mark (X) the box at the right. → ☐

You do not have to answer linkage questions for items in subsection 1 if you make this claim. If you want to claim items in this subsection individually, do not mark the box.

Place the letter(s) A–G in the confidential code box next to any item you claim as confidential to indicate the basis of your claim. Answer the linkage questions in the **Instructions Manual** for categories A–F.

Confidential code

DRAFT

1. Estimate the maximum annual production volume during the first three years of production or import. Include in your estimates production by others with whom you have contracted to manufacture the new chemical substance.

Period covered *(Mo./yr.)* (1)		Maximum volume (kg/yr) (2)	Confidential code
From	To		

3. Category of use —

If you claim the category "Use Information" as confidential, mark (X) the box at the right. → ☐

You do not have to answer linkage questions for items in subsection 3 if you make this claim. If you want to claim items in this subsection individually, do not mark this box.

You must claim the description of the category of use and the use information related to that category separately. Place the letters A–G in the confidential code box next to any item that you claim as confidential to indicate the basis of your claim. Answer the linkage questions in the **Instructions Manual** for categories A–F.

a. List the categories of use on which you based your production estimates. Give as complete a description as possible. Read the **Instructions Manual** for examples. Estimate the percent of total production for the first three years devoted to each category of use. Mark (X) the use if site limited.

Category of use (1)	Confidential code	Production percent (2)	*Mark (X) if site limited* (3)	
		%		
		%		
		%		

☐ *Mark (X) this box if you attach a continuation sheet.*

b. Generic use description — If you claim any category of use description in subsection 3, item (a) as confidential, enter a generic description of that category. Read the **Instructions Manual** for guidance in developing the generic description.

☐ *Mark (X) this box if you attach a continuation sheet.*

4. Hazard information – Attach a copy or reasonable facsimile of any hazard warning statement, label, labeling, marking or instructions, technical data sheet, material safety data sheet, and any other information which will be provided to any person regarding the safe handling, transport, use, disposal, treatment upon accidental exposure, or the formulation, construction, or labeling of products containing the new chemical substance. Read the **Instructions Manual** for instructions on claiming and substantiating confidential information in attachments. List in part III any hazard information you attach.

☐ *Mark (X) this box if you attach hazard information*

DRAFT

Part II – HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE

Section A – SITES CONTROLLED BY THE SUBMITTER

Complete a separate section A for each operation at an industrial site where you will manufacture, process, or use the new chemical substance.

If you claim the category "Process Information" as confidential, mark (X) the box at the right. → ☐

You do not have to answer linkage questions for items in subsection 1 if you make this claim. If you want to claim items in this category individually, do not mark the box.

Place the letter(s) A–G in the confidential code box next to any items you claim as confidential to indicate the basis of your claim. Answer the linkage questions in the **Instructions Manual** for categories A–F.

Confidential code

DRAFT

1. Operation description

a. Type
Mark (X)

1 ☐ Manufacturing 2 ☐ Processing 3 ☐ Use

b. Duration Hours/day

Days/year

c. Diagram

Provide a diagram identifying the following:

(1) Major unit operations and chemical conversions.

(2) The approximate weight of all materials (including feedstocks, reactants, byproducts, coproducts, solvents, catalysts and surfactants) entering the process.

(3) Materials (including feedstocks, reactants, byproducts, coproducts, solvents, catalysts and surfactants) leaving the process.

(4) Identify those materials that will be incinerated.

☐ *Mark (X) this box if you attach a continuation sheet.*

DRAFT

Part II – HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE – Continued

DRAFT

Section A – SITES CONTROLLED BY THE SUBMITTER – Continued

2. Occupational Exposure at Industrial Site

a. Occupational exposure

(1) – Indicate the physical form(s) of the new chemical substance at the time of exposure for any individual worker.

(2) – Enter the number of workers anticipated to be exposed during each activity.

(3) and (4) – Enter the maximum exposure for any individual worker in hours per day and days per year.

Physical form(s) (1)	Maximum number exposed (2)	Maximum duration Hrs/day (3)	Days/yr (4)	Confidential code

☐ *Mark (X) this box if you attach a continuation sheet.*

3. Environmental Release and Disposal

a. Release and Disposal Data

For releases of the new chemical substance to air and water, identify the source of release and the type of release control technology. For releases disposed on land, indicate the source of the release and characterize the disposal method. Mark (X) the destination of the water discharge.

Media	Source (a)	Control technology *(Type)* (b)	Duration of release Hrs/day (c)	Days/yr (d)	
(1) Air					
(2) Water					
(3) Land					

Mark (X) one

1 ☐ POTW (Publicly Owned Treatment Works) 2 ☐ Navigable waterway 3 ☐ Other

Part III – LIST OF ATTACHMENTS

DRAFT

If you use additional copies of part II, sections A or D, insert these sections after the corresponding section of the notice form. If you submit attachments to any subsection or item, insert the attachment after the page containing the subsection or item. Attach test data, optional information, and confidentiality attachments after the last page of the form.

Number the pages of the completed Premanufacture Notice consecutively from the first page of the notice form to the last page of your last attachment. Write the name of the attachment in the appropriate spaces below. In the column to the right, give the inclusive page numbers for additional sections of the form and attachments to subsection or items and give the number of the first page of test data and optional information attachments. When listing confidentiality linkage and substantiation attachments, identify the part, section, subsection, or item of the form to which they apply.

Place the letter(s) A–G in the confidential code box next to any attachment name that you claim as confidential to indicate the basis of your claim. Answer the linkage questions in the **Instructions Manual** for categories A–F. This claim constitutes a claim only for the attachment name not for any information in the attachment.

Read the **Instructions Manual** for information on how to claim any information in an attachment as confidential. You must submit a copy of the attachment with all the information that you claim as confidential deleted. EPA will place this sanitized copy in the public file. List sanitized copies in the "Confidentiality Attachments" space.

	Attachment name	Attachment page number(s)	Confidential code
a. Notice form sections and attachments			
b. Environmental fate data			
c. Health and environmental effects data			
d. Optional information			

	Part	Section	Subsection	Item	Attachment page number(s)	Confidential code
e. Confidentiality attachments (Linkage and substantiation)						

☐ *Mark (X) this box if you attach a continuation sheet. Enter the attachment number.*

FORM EPA 7710-25 (4-3-82)

PART IV – OPTIONAL INFORMATION

DRAFT

A reasoned evaluation of the health and environmental effects of a new chemical substance requires data on the chemical's properties, production volume, worker exposure, and environmental release. Parts I and II of the form request this information. Other factors, however, can affect EPA's analysis of risk. This optional part gives you the opportunity to provide additional information that you believe EPA should consider in evaluating potential risks associated with the chemical substance and to present your analysis of information given in the mandatory sections of the form. Listed below are categories of information which may be included in this part. You may include information on subjects not mentioned here. Read the "Instructions Manual for Premanufacture Notification" for guidance on how to claim information in attachments confidential.

RELATIVE RISK ANALYSIS

Compare the health and environmental risk of the manufacture, processing, use, or disposal of the new chemical substance to the risk of substances currently in use. State whether or not the new substance will be less toxic than substances which it may or will replace. Indicate whether or not workers exposed to the new substance in production or processing will face a lower risk than they would if the substance were withheld from production. State whether or not a net decrease in the amount of toxic substances released into the environment will result from the new chemical's production. Specify the methodology used in determining any reduction of risk.

PROCESS CHEMISTRY

Provide information on process chemistry controls that limit impurity or byproduct concentrations. Such information might explain that a particular reaction was chosen and that temperature control, pressure control, or continuous monitoring is used to limit these concentrations.

EFFICACY INFORMATION

Attach any efficacy data or product bulletins you may have on the new chemical substance.

ADDITIONAL EXPOSURE AND ENVIRONMENTAL RELEASE INFORMATION

Attach any additional exposure and environmental release information you may have. Such information may include specific time-weighted averages for durations, concentrations, and amounts, the minimum monitorable levels of the new chemical substance, its impurities and byproducts in the workplace or in effluent, and anticipated transportation exposure. If there are differences among sites, describe these differences. Provide data on releases from equipment used to produce the new chemical substance when you also use this equipment to produce other substances. Describe any market studies that identify consumers by age, geographic location, or other factors. Identify any environmental impact statements or similar documents about manufacturing or processing facilities and landfill sites previously submitted to government agencies. Provide any such documents you have not submitted to any agency.

ADDITIONAL PRODUCTION INFORMATION

Indicate whether the estimates of anticipated production volume in the form are based on firm orders or forecasts. Provide any explanation which may assist EPA in determining whether your estimates of production volume may be higher or lower than your actual production.

INDUSTRIAL HYGIENE

Describe the major aspects of any industrial hygiene programs you will establish to reduce the risk to workers posed by exposure to the new chemical substance. Such programs may include chemical hazard education, exposure monitoring, physical protection measures, chemical emergency evacuation procedures, and health examinations. Explain how these programs reduce risk. If programs differ among sites, explain these differences.

ENGINEERED SAFEGUARDS

Attach a description of design features in the manufacture, processing, use, or disposal of the new chemical substance which limit the risk to health and the environment. Such a description may examine both workplace safeguards and environmental release safeguards. Indicate the function and efficiency of each safeguard. Note its relation to exposure information included in parts I and II. If the safeguards used vary among sites, explain why.

USE RESTRICTION INFORMATION

Explain any restrictions on use or other control of the new chemical substance not addressed in other sections of this form which should be considered by EPA in its assessment of the risk associated with the substance.

ECONOMIC AND NON-ECONOMIC BENEFITS

Explain why the economic or non-economic benefits of the new chemical substance make the risks associated with its manufacture, processing, use, or disposal reasonable. State, for example, whether or not the production of substance directly or indirectly affects human health or safety, improves environmental quality, conserves energy, or substantially affects employment or balance of trade.

LIST ALL ATTACHMENTS TO THIS OPTIONAL PART IN PART III, LIST OF ATTACHMENTS

FORM EPA-7710-25 (4-8-82)

DRAFT

PREMANUFACTURE NOTICE
FOR NEW CHEMICAL SUBSTANCES

AGENCY USE ONLY

Date of receipt

When completed send this form to:

DOCUMENT CONTROL OFFICER
OFFICE OF TOXIC SUBSTANCES, TS-793
U.S. E.P.A.
401 M STREET, SW
WASHINGTON, D.C. 20460

Enter the total number of pages in the Premanufacture Notice

Document control number

EPA case number

GENERAL INSTRUCTIONS

You must provide all information requested in this form to the extent that it is known to or reasonably ascertainable by you. Make reasonable estimates if you do not have actual data. If you do not know or cannot reasonably ascertain this information, enter "NK" (not known or reasonably ascertainable).

Before you complete this form you should read the "Instructions Manual for Premanufacture Notification of New Chemical Substances."

Part I. GENERAL INFORMATION

You must provide the chemical identity of the substance, even if you claim the identity as confidential. You may authorize another person to report the identity for you, but your submission will not be complete and review will not begin until EPA receives this information.

Part II. HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE

You may need additional copies of part II, sections A and B if there are several manufacture, processing, or use operations that you will describe in the notice. You may obtain these additional sections from the Office of Toxic Substances Industry Assistance Office.

Part III. LIST OF ATTACHMENTS

You should attach additional sheets if you do not have enough space on the form to answer a question fully. In part III, list these attachments, any test data or other data, and optional information that you include in the notice.

OPTIONAL INFORMATION

You may include in the Notice any information that you want EPA to consider in evaluating the new substance. The **Instructions Manual** identifies categories of optional information that you may want EPA to review.

CONFIDENTIALITY CLAIMS

You may claim any information in this notice as confidential. To assert a claim, mark (X) the confidential box on the form associated with the information that you claim as confidential. If you claim information in the Notice as confidential, you must provide a sanitized version of the Notice, including attachments, to EPA with your submission. For additional instructions on claiming information as confidential and subtantiating confidentiality claims, read the **Instructions Manual.**

Indicate below the categories of information you have claimed as confidential.

☐ SUBMITTER IDENTITY
☐ CHEMICAL IDENTITY
☐ PRODUCTION VOLUME
☐ USE INFORMATION
☐ PROCESS INFORMATION
☐ PORTIONS OF A MIXTURE
☐ OTHER INFORMATION

TEST DATA AND OTHER DATA

You are required to submit all test data in your posession or control and to provide a description of all other data known or reasonably ascertainable if these data are related to the health and environmental effects of the manufacture, processing, distribution in commerce, use, and disposal of the new chemical substance. Complete test data, not summaries of data, must be submitted. Following are examples of test data and other data. You should submit these data according to the requirements of §720.50 of the Premanufacture Notification Rule.

Test data

- **Environmental fate data**
  - Spectra (UV and visible)
  - Density of liquids and solids
  - Water solubility
  - Melting point/melting range
  - Boiling point/boiling range
  - Vapor pressure
  - Partition coefficient, n-octanol/water
  - Biodegradation
  - Hydrolysis (as a function of pH)
  - Photochemical degradation
  - Adsorption/desorption to soil types
  - Dissociation constant
  - Other physical/chemical properties
- **Health effects data**
  - Mutagenicity
  - Carcinogenicity
  - Teratogenicity
  - Acute toxicity
  - Repeated dose toxicity
  - Metabolism studies
  - Sensitization
  - Irritation
- **Environmental effects data**
  - Microbial and algal toxicity
  - Terrestrial vascular plant toxicity (e.g., seed germination studies, growth inhibition)
  - Acute and chronic toxicity to animals (e.g., fish, birds, mammals, invertebrates)

Other data

- **Risk assessments**
- **Structure/activity relationships**
- **Test data not in the possession or control of the submitter**

EPA Form 7710-25 (12-20-82)

CERTIFICATION

I certify that to the best of my knowledge and belief:

1. The company named in part I, section A, subsection 1, of this notice form intends to manufacture or import for a commercial purpose, other than in small quantities for research and development, the substance identified in part I, section B.
2. All information provided in this notice is complete and truthful as of the date of submission.
3. I am submitting with this notice all test data in my possession or control and a description of all other data known to or reasonably ascertainable by me as required by §720.50 of the Premanufacture Notification Rules.

I will allow an authorized representative of the EPA Administrator to examine and copy records in accordance with the Toxic Substances Control Act to document any information in this notice.

Signature of authorized official	Date	Confidential

Part I — GENERAL INFORMATION

Section A — SUBMITTER IDENTIFICATION

Mark (X) the "Confidential" box next to any subsection you claim as confidential.

1. Person submitting notice

Name of authorized official | Title

Company

Mailing address (number and street)

City, State, ZIP code

Mark (X) appropriate box(es) ☐ Manufacturer ☐ Agent ☐ Joint submission

2. Technical contact

Name | Title

Mailing address (number and street)

City, State, ZIP code | Telephone | Area code | Number

3. If you have had a prenotice communication (PC) concerning this notice and EPA assigned a PC Number to the notice, enter the number — *Mark (X) if none* ☐

4. If you have submitted a test marketing exemption (TME) application for the chemical substance covered by this notice, enter the TME number assigned by EPA — *Mark (X) if none* ☐

5. If you have submitted a bona fide request for the chemical substance covered by this noticce, enter the bona fide request number assigned by EPA — *Mark (X) if none* ☐

6. Type of Notice — *Mark (X)* ☐ Manufacture ☐ Import

CONTINUE WITH PART I ON PAGE 3.

FORM EPA-7710-25 (12-20-82)

Part I — GENERAL INFORMATION — Continued

Section B — CHEMICAL IDENTITY

Mark (X) the "Confidential" box next to any item you claim as confidential.

Complete either item 1 or 2 as appropriate. Complete all other items.

If another person will submit chemical identity information for you, mark (X) the box at the right. Identify the name, company, and address of that person in a continuation sheet. ☐

Confi-dential

1. Class 1 or 2 chemical substance (for definitions of class 1 and class 2 substances, see the **Instructions Manual**)

Mark (X) class of substance 1 ☐ Class 1 2 ☐ Class 2

a. Chemical name (preferably CAS or IUPAC nomenclature)

b. Molecular formula and CAS Registry Number (if known)

c. For a class 1 substance, provide a structural diagram. For a class 2 substance — (1) List the immediate precursor substances with their respective CAS Registry Numbers. (2) Describe the nature of the reaction of process. (3) Indicate the range of composition and the typical composition (where appropriate). (4) Provide a representative structural diagram (if possible).

☐ *Mark (X) this box if you attach a continuation sheet.*

FORM EPA-7710-25 (12-20-82)

Part I — GENERAL INFORMATION — Continued

Section B — CHEMICAL IDENTITY — Continued

Confidential

2. Polymers

a. Estimate the **lowest** number-average molecular weight composition of the polymer you intend to manufacture. Estimate the **maximum** weight percent of low molecular weight species below 500 and below 1000 absolute molecular weight. Describe the method of measurement or the bases for your estimates.

☐ *Mark (X) this box if you attach a continuation sheet.*

b. (1) — Provide chemical names and CAS Registry Numbers of monomers and other reactants used in the manufacture of the polymer.
(2) — Provide the **typical** composition of the monomer or reactant in the polymer in percent (by weight).
(3) — Mark (X) the identity column if you want a monomer used at two percent (by weight) or less to be listed as part of the polymer description on the Chemical Substance Inventory.
(4) — Estimate the **maximum** amount of the monomer or reactant in percent (by weight) that may be present as a residual in the polymer as distributed in commerce.

Monomer or reactant and CAS Registry Number (1)	Typical composition (2)	Identity *Mark (X)* (3)	Maximum residual (4)
	%		%
	%		%
	%		%
	%		%
	%		%
	%		%
	%		%

☐ *Mark (X) this box if you attach a continuation sheet.*

c. Provide a representative structural diagram of the polymer, if possible.

☐ *Mark (X) this box if you attach a continuation sheet.*

FORM EPA-7710-25 (12-20-82)

Part I — GENERAL INFORMATION — Continued

Section B — CHEMICAL IDENTITY — Continued

3. Impurities

(a) — List each impurity, including CAS Registry Number, that may reasonably be anticipated to be present in the chemical substance as it will be manufactured for commercial purposes.

(b) — Estimate the maximum percent (by weight) of each impurity. If there are unidentified impurities, estimate the percent of unidentified impurities (by weight).

Impurity and CAS Registry Number (a)	Maximum percent (b)	Confidential
	%	
	%	
	%	
	%	
	%	
	%	
	%	

☐ *Mark (X) this box if you attach a continuation sheet.*

4. Synonyms — Enter any synonyms for the new chemical substance named in subsections 1 or 2.

☐ *Mark (X) this box if you attach a continuation sheet.*

5. Trade identification — List trade names for the new chemical substance named in subsections 1 or 2.

☐ *Mark (X) this box if you attach a continuation sheet.*

6. Generic chemical name — If you claim chemical identity as confidential, enter the generic chemical name that was accepted by EPA in prenotice communication or provide a generic name that reveals the specific chemical identity of the new chemical substance to the maximum extent possible. Read the **Instructions Manual** for guidance on developing generic names.

☐ *Mark (X) this box if you attach a continuation sheet.*

7. Byproducts — Describe any byproducts associated with the manufacture, processing, use, or disposal of the new chemical substance. Provide the CAS Registry Number if available.

Byproduct (1)	CAS Registry Number (2)	

☐ *Mark (X) this box if you attach a continuation sheet.*

Part I— GENERAL INFORMATION — Continued

Section C — PRODUCTION, IMPORT, AND USE DATA

Mark (X) the "Confidential" box next to any item you claim as confidential.

1. Provide an estimate of the **maximum** production volume during the first 12 months of production. Also provide an estimate of the **maximum** 12-month production volume during the first three years.

Maximum first 12-month production (kg/yr)	Maximum 12-month production (kg/yr)	Confidential

2. **Use Information**

You must make separate confidentiality claims for the description of the ccategory of use, the formulation of the new substance as distributed in commerce, and other use information. Mark (X) the "Confidential" box next to any item you claim as confidential.

a. Describe the intended categories of use by function and application. Estimate the percent of total production for the first three years devoted to each category of use. Estimate the percent of the new substance as formulated in mixtures, suspensions, emulsions, solutions, or gels as distributed in commerce. Mark (X) whether the use is site-limited, industrial, commercial, or consumer. Mark more than one box if appropriate. Read the **Instructions Manual** for examples.

Category of use (1)	Confidential	Production percent (2)	Confidential	Formulation (percent) (3)	Confidential	*Mark (X) appropriate column(s)* (4)				
						Site limited	Industrial	Commercial	Consumer	
		%		%						
		%		%						
		%		%						
		%		%						

☐ *Mark (X) this box if you attach a continuation sheet.*

b. Generic use description — If you claim any category of use description in subsection 2, item (a) as confidential, enter a generic description of that category. Read the **Instructions Manual** for examples of generic descriptions.

☐ *Mark (X) this box if you attach a continuation sheet.*

3. Hazard Information — Include in the notice any copy or reasonable facsimile of any hazard warning statement, label, material safety data sheet, and other information which will be provided to any person regarding the safe handling, transport, use, or disposal of the new chemical substance. List in part III any hazard information you include.

☐ *Mark (X) this box if you attach hazard information.*

Part II — HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE

Section A — INDUSTRIAL SITES CONTROLLED BY THE SUBMITTER

Complete section A for each type of manufacture, processing, or use operation involving the new chemical substance at industrial sites you control.

Confi-dential

Mark (X) the "Confidential" box next to any item you claim as confidential.

1. Operation description

a. Identity— Enter the identity of the site at which the operation will occur.

Name

Site address (number and street)

City, County, State, ZIP code

If the same operation will occur at more than 1 site, enter the number of sites.—
Identify the additional sites on a continuation sheet.

☐ ***Mark (X) this box if you attach a continuation sheet.***

b. Type — *Mark (X)* 1 ☐ Manufacturing 2 ☐ Processing 3 ☐ Use

c. *Mark (X)* 1 ☐ Continuous 2 ☐ Batch

d. Amount and Duration — *Mark (X)*	Batch	Maximum kg/batch	Hours/batch	Batches/year
	Continuous	Maximum kg/day	Hours/day	Days/year

e. Process description
(1) Diagram the major unit operations steps and chemical conversions.
(2) Provide the identity, the approximate weight (by kg/day or kg/batch), and entry point of all feedstocks (including reactants, solvents, and catalysts).
(3) Identify by number the points of release of the new chemical substance.

☐ ***Mark (X) this box if you attach a continuation sheet.***

Part II — HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE — Continued

Section A — INDUSTRIAL SITES CONTROLLED BY THE SUBMITTER — Continued

2. Occupational Exposure

You must make separate confidentiality claims for the description of worker activity, physical form of the new chemical substance, and other exposure information. Mark (X) the "Confidential" box next to any item you claim as confidential.

(1) — Describe the activities in which workers may be exposed to the new chemical substance. Include activities in which workers wear protective equipment.
(2) — Indicate the physical form(s) of the new chemical substance at the time of exposure.
(3) — Enter the maximum number of workers involved in each activity.
(4) and (5) — Enter the maximum duration of the activity for any worker in hours per day and days per year.

Worker activity (1)	Confidential	Physical form(s) (2)	Confidential	Maximum number (3)	Maximum duration		Confidential
					Hrs./day (4)	Days/yr. (5)	

☐ *Mark (X) this box if you attach a continuation sheet.*

3. Environmental Release and Disposal

You must make separate confidentiality claims for the release number and amount of new chemical substance released and other release and disposal information. Mark (X) the "Confidential" box next to each item you claim as confidential.

(1) — Enter the number of each release point identified in part II, section A, item c.
(2) — Enter the amount of new chemical substance released into control technology in kilograms per day or kilograms per batch.
(3) — Identify the media (air, land, or water) to which the new substance will be released from that point.
(4) — Describe control technology, if any, that will be used to limit the release of the new substance to the environment. For releases disposed on land, characterize the disposal method.
(5) — Mark (X) the destination(s) of releases to water.

Release Number (1)	Amount of new substance released (2)	Confidential	Media of release (3)	Control technology (Type) (4)	

(5) Mark (X) the destination(s) of releases to water.

1 ☐ POTW (Publicly Owned Treatment Works)

2 ☐ Navigable waterway

3 ☐ Other — *Specify* ________________

FORM EPA-7710-25 (12-20-82)

Part II — HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE — Continued

Section B — INDUSTRIAL SITES CONTROLLED BY OTHERS

Complete section B for each type of processing or use operation involving the new chemical substance at sites you do not control. *Mark (X) the "Confidential" box if you claim this section as confidential.*	Confi-dential
1. Operation description Briefly describe the typical operation. Estimate the number of sites at which the operation will occur. Identify situations in which worker exposure to and/or environmental release of the new chemical substance will occur. Estimate the percent formulation of the new chemical substance as processed or used in the operation. Estimate the number of workers exposed and the duration of exposure. Identify controls which limit worker exposure and environmental release if typically used. Identify byproducts which may result from the operation.	☐

☐ *Mark (X) this box if you attach a continuation sheet.*

Part III — LIST OF ATTACHMENTS

Attach any continuation sheet for sections of the form, test data and other data (including physical/chemical properties and structure/activity information), and optional information, after the last page of the form. Clearly identify the attachment and the section to which it relates, if appropriate. Number consecutively the pages of the attachments. In the column below, enter the inclusive page numbers of each attachment.

Mark (X) the "Confidential" box next to any attachment name you claim as confidential. Read the **Instructions Manual** for guidance on how to claim any information in an attachment as confidential. You must include with the sanitized copy of the notice a sanitized version of any attachment in which you claim information as confidential.

Attachment name	Attachment page number(s)	Confi-dential

☐ *Mark (X) this box if you attach a continuation sheet. Enter the attachment name and number.*

FORM EPA-7710-25 (12-20-82)

APPENDIX H

ANALYSIS OF TEST-MARKETING EXEMPTION PROVISION OF THE PMN RULE

A. INTRODUCTION

Section 5(h)(1) of the Toxic Substance Control Act authorizes EPA to grant exemptions from any requirements of section 5(a) or 5(b) of the Act for test-marketing purposes. To grant a test-marketing exemption (TME), the Agency must find that the test marketing will not present any unreasonable risk of injury to health or the environment. Section 5(h)(6) provides that EPA must either approve or deny the application within 45 days of its receipt and must publish a notice of its decision in the Federal Register. EPA may impose restrictions on the test-marketing activities if it grants an exemption.

In order to grant a test-marketing exemption the Agency must find that the chemical will not present any unreasonable risk of injury to health or the environment. In contrast, EPA need not make this affirmative finding when it reviews a PMN. Instead, EPA does not act on a PMN chemical (and allows manufacture to begin) unless if finds that the chemical may present an unreasonable risk to society. Thus, the rigor of analysis needed to make the TME finding exceeds that needed to allow a PMN chemical to proceed into production. In the case of TME applications, TSCA clearly places the burden of proof on the company. Because the company must make this case, some TME applications can be more costly than PMNs.

In the PMN RIA, four costs associated with the information requirement were derived. These cost elements were form-filing costs, delay costs, confidentiality costs, and costs of restrictive actions. In addition, incremental benefits associated with alternative information requirements were determined.

At first glance, it seems that TME applications result in the same set of costs and benefits as PMNs and can be analyzed in the same manner PMNs were. However, several factors unique to TMEs undermine this approach. As mentioned above, EPA must make a finding of no unreasonable risk for TME chemicals, but not for PMN chemicals. This requirement means it is possible that review of a TME chemical will result in a request for additional information which leads the company to withdraw the TME and file a PMN (this situation has actually occurred). The PMN may subsequently be allowed to go into production without further scrutiny. This problem complicates the process of estimating benefits of the TME program. That is, the TME program resulted in the withdrawal of the chemical from a test-marketing program only to have it be allowed to go into commercial production (if the product is actually manufactured). Obviously, no health benefit is gained by society from this result.

Second there is the problem of defining specifically what the information requirement is. For PMNs, a form must be completed, but the final rule requires only that a TME applicant provide certain information in any form it chooses. The information requirements of the rule are suggestive, not truly definitive, and the Agency may request that the applicant provide additional information so EPA can make its determination. Because no form exists and because the required information varies with the particular chemical, use of the PMN costing approach (an approach based on how much time it takes to complete various information segments specified in the regulation) is misleading. Instead, direct analysis of information required to assess TMEs in the past is more appropriate.

The third complexity associated with TME analysis concerns delay costs. For a PMN, the delay elements consisted of the time required for the company to complete the PMN and the time required for EPA review. Every PMN chemical that entered production within 30 days of the end of the review period was assumed to have been delayed. Because TME chemicals are going into test marketing, not full-scale production, the use of this approach to measure delay costs results in no delay costs (none have entered production). On the other hand, it does take time to provide EPA with information, and TSCA allows EPA 45 days in which to make a finding.

Because of these problems, it appears that only two of the five elements explored in the PMN analysis can be approached in a manner consistent with the PMN approach. Restrictive action costs are by far the most important cost element.

The rest of this paper explores the costs and benefits of the TME provisions in the final rule. Before determining the costs and benefits of the rule, we examine a sample of approximately 40 TMEs out of the total (175) submitted between July 1979 and December 1982 to determine the characteristics of TMEs (who submits them, what are typical production volumes, what kinds of actions are taken by the Agency, etc.), and through this characterization define an analysis appropriate to TMEs. Using the sample as the basis for our analysis, we determine filing costs, delay costs, confidentiality costs, and restrictive action costs. This is followed by a discussion of the benefits of the TME process. We conclude by comparing and summarizing the costs and benefits.

B. CHARACTERISTICS OF TEST MARKETING EXEMPTIONS

This section describes the characteristics of test-marketing exemption chemicals (TMEs). It begins with a description of the methodology used to determine these characteristics. This description is followed by a summary of the results of the analysis.

About 40 TME applications submitted by more than 20 firms were selected at random from the total number submitted to EPA during the period July 1979 to December 1982. The information collected for each TME application included production volume, firm name and size, whether or not the chemical was imported, use of the chemical, and details of any EPA action or voluntary action by the applicant. This information was tabulated and analyzed in order to reveal any trends or correlations which might be characteristic of TMEs. The results of this analysis are discussed in turn.

The tabulation of the production volumes of the TMEs reveals that these chemicals are generally produced in small amounts (see Exhibit H-1). Nearly half (46 percent) of the forty-one TME applications specified production volumes less than one thousand kilograms. Twenty-two percent of the TMEs had production volumes between one thousand and five thousand kilograms. The remaining third of the applications indicated production volumes greater than five thousand kilograms (10 percent between five and ten thousand kilograms; twenty-two percent greater than ten thousand kilograms), up to a maximum of fifty-one thousand kilograms.

The analysis shows that most of the firms applying for exemption are relatively large (see Exhibit H-2). None of the companies had sales under two hundred million dollars per year. Only one of twenty-four firms reported annual sales under five hundred million dollars. Only 13 percent of the

EXHIBIT H-1

DISTRIBUTION OF PRODUCTION VOLUMES

Production Volume (Kilograms)	Percent of Sample
0 - 999	46
1000 - 4999	22
5000 - 9999	10
10000 or more	22

EXHIBIT H-2

DISTRIBUTION OF FIRM SIZES

Annual Sales (millions of $)	Percent of Sample
0 - 199	0
200 - 499	>5
500 - 999	13
1000 - 1999	25
2000 - 4999	29
5000 or more	29

companies had sales between five hundred million and one billion dollars. Over eighty percent of the companies had sales of one billion dollars or more. Almost thirty percent of the firms reported sales exceeding five billion dollars, up to a maximum of twenty-five billion dollars.

The distribution of intended uses for the TME chemicals resembles the distribution of uses for premanufacture notifications (see Exhibit H-3). The largest single use category for both TME and PMN chemicals is paints and coatings, followed by chemical intermediates and plastics. The two use distributions, however, do diverge in several respects. For example, a much greater proportion of TME chemicals are used in inks and to produce other

EXHIBIT H-3

DISTRIBUTION OF USES

Use	Number of TMEs	Percent of Sample	Percent of PMNs[1]
Chemical Intermediate	7	29	18
Wood Treatment	<5	<10	<1
Paper Processing	<5	<10	<1
Petroleum Production	<5	<10	1
Plastics	<5	10	12
Rubber and Elastomers	<5	<10	1
Chemical Production	5	12	2
Dyes and Pigments	<5	<10	7
Inks and Printing	<5	<10	1
Photographic Chemicals	<5	<10	4
Paints and Coatings	9	22	24
Coatings Additives	<5	<10	6
Automotive Chemicals	<5	<10	2
Unknown	<5	<10	3

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[1] These percent figures do not total 100 percent because the uses of the TME chemicals in the sample do not cover the whole spectrum of uses for PMN chemicals.

chemicals than the proportion of PMN chemicals put to the same uses. Conversely, more PMN chemicals than TME chemicals are used as dyes.

The analysis also includes the nature and frequency of EPA actions and voluntary actions on the part of the firm (see Exhibit H-4). In the vast majority of the cases examined (85 percent), EPA granted the TME without taking any action (i.e., denying the application or asking the applicant for additional data). Based on information provided in the TME application, EPA was usually able to make the decision that the test-marketing activity did not present any unreasonable risk to health or the environment. In one case, EPA took no action because the applicant was not the manufacturer, and in another, the manufacturer requested that the application be withdrawn. EPA requested additional information for five of the TME chemicals. Three of the applicants supplied the information requested; these TME applications were subsequently granted. The other two applicants did not supply the additional information even after repeated requests. EPA denied these TME applicants, having insufficient information to positively determine that no unreasonable risk would occur. One of the latter two applicants intended to submit a PMN in the near future. EPA requested one of the applicants to submit a revised Material Safety Data Sheet (MSDS). The applicant complied, and EPA granted the exemption.

EXHIBIT H-4

EPA ACTIONS ON THE APPLICATIONS IN SAMPLE

EPA Action	Number of TMEs	Percent of Sample	Voluntary Action	Granted	Denied	Withdrawn	Invalid
No Action	36	85.4	0	34	0	1	1
Requested Information	5	12.2	3	3	2	0	0
Requested MSDS Change	<5	<5	<5	<5	0	0	0

Almost ten percent of the TME applicants planned to import their product. All four were granted exemptions without additional EPA action. There are no observable correlations in the production volumes, firm sizes, or uses of the imported chemicals.

Several cross-tabulations were performed on the data to identify possible correlations between various aspects of the information. There is no correlation between production volume and EPA action, use and EPA action, or production volume and voluntary action. The absence of observable correlations between these specific data may be a function of the small sample size. It seems possible that a correlation between SAT score (level of concern) and EPA restrictive action exists, although Structure Activity Term (SAT) scores for some TME chemicals could not be obtained.

The analysis presented here may be used to characterize TME chemicals. According to this analysis, TME applications are usually submitted by large firms for relatively small volumes of the chemical. Most of the exemptions are granted without any additional EPA action, indicating that most of the applicants submit sufficient information for EPA to determine that the test marketing will not pose an unreasonable risk to health or the environment. The distribution of uses for the TME chemicals resembles that of PMN chemicals.

The fact that this profile of TME applications was developed from a study of about forty of 175 TME applications received from 1980 to 1982 could limit its accuracy and usefulness. Despite the limited sample size, however, the results of this analysis seem to make sense. Test marketing, by definition, involves a small number of customers. It is reasonable to expect that the production volumes would be small. Under TSCA, EPA has only forty-five days to decide whether to grant a TME. As a result, the burden is upon the applicant to prove that the test-marketing program would not present an unreasonable risk to health or the environment. It seems reasonable to expect that EPA would have time only to grant or deny the exemption in the majority of cases, rather than enter potentially protracted activities to determine or limit exposure. The high proportion of exemptions granted could be related to the relatively low production volumes, which reduce the potential for exposure to the TME chemicals. Thus, despite the small sample size, the profile developed from this analysis provides a useful qualitative characterization of TMEs.

C. COSTS

1. Filing Costs

One part of the cost analysis of TME applications is determining the amount of information provided by applicants, and the cost to provide it. As discussed in the introduction, the information requirement is open-ended. There is no standard form for TME submissions and the rule requires only that the submitter provide enough information so that EPA can ascertain that there will be no possibility of unreasonable risk to human health or the environment. Thus, for this analysis, the cost estimate is based on a retrospective examination of information provided by submitters both initially and as required by the Agency during its review of the TME.

Submitters of TMEs in our sample generally provided considerable information using either the EPA79 PMN form or on a modified version of it. By matching sections of the EPA79 form with the data provided by individual submitters, previous costing methodologies (ADL 1979 pp. 32-38 and Chapter IV of this paper) were used to estimate the cost to submit the typical TME application. The approach taken was to determine which pieces of information each of the submitters provided and to then determine the total cost for that submitter to submit the TME, assuming that it took the amount and type of labor estimated for that section in earlier studies. The guidelines for determining whether a submitter had provided a section of information were:

(1) If, in a given section, the submitter could complete either one subsection or another subsection, but not both, then the section was considered completed if either was provided. This results in neither an overestimate nor an underestimate of the cost.

(2) Except for the chemical identification section, if any subsection of a section was filled out, then the section was considered completed. Filling out the chemical identification section is more complicated in that information in any one of the subsections is not necessarily indicative of the time requirement for supplying chemical identification. Therefore, only the submitters that supplied at least the specific chemical name were counted as filling out the chemical identification section. By accounting for only the submitters that supplied a specific chemical name, a more accurate view of the costs for the chemical identification section was seen. This causes an overstatement of the costs.

(3) If any information was provided for a section it was considered completed, regardless of whether it was a substantial amount of information or not. This also causes the costs to be overstated.

The net effect of these rules is to overestimate the filing costs.

Exhibit H-5 shows the fraction of the TMEs providing information in each section and computes an adjusted hour completion estimate for the typical TME application.

As shown in Exhibit H-5, the percent of submitters that filled out the various parts of the form was tabulated and these percentages were used to derive TME labor hour requirements. The labor cost estimates of \$17/hour clerical, \$43/hour technical, and \$67/hour managerial (Appendix A) were multiplied by the hours to create a range of costs for TME submissions. Exhibit H-6 shows these results:

EXHIBIT H-5

LABOR REQUIREMENTS FOR TME APPLICATIONS[c]

Section of Notice	Fraction of Total (41)	% of Total	Adjusted # of Hours Clerical	Adjusted # of Hours Technical	Adjusted # of Hours Management
I. General Information	41/41	100	2-10	-	-
A. Manufacturer Identification	41/41	100	-	-	1-8
B. Chemical Identity b/					
1. Class I Chemical Substance a/	34/41	083	-	0.8-3.3	-
2. Class II Chemical Substance a/	-	-	-	-	-
3. Polymers a/	-	-	-	-	-
4. Impurities	13/41	032	-	0.3-2.6	-
C. Generic Names	13/41	032	-	0-1.3	0-0.3
D. Production and Marketing Data b/	26/41	063	-	-	0.6-1.3
1. Production Volume	26/41	063	-	0.6-2.5	-
2. Category of Use	26/41	063	-	0.6-5.0	-
3-4. Previous Manufacture and Hazardous Warnings	7/41	017	-	0.2	-
5. Customers	12/41	029	-	0-2.3	-
E. Transport	9/41	022	-	0.2	-
F. Risk Assessment	16/41	039	-	0-6.2	0-0.8
G. Detection Methods	0/41	0	-	0	-

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c/Based on analysis of similar data segments found in the EPA79 PMN form.

a/Every chemical is either in Class I, Class II, or is a polymer and therefore, only one of subsections I.B.1, I.B.2, and I.B.3 will be submitted. Thus, only one of these subsections was filled because it reflects both the minimum and the maximum possible labor requirements needed for a chemical substance.

b/At least some information provided.

EXHIBIT H-5
(continued)

LABOR REQUIREMENTS FOR TME APPLICATIONS

Section of Notice	Fraction of Total (41)	% of Total	Adjusted # of Hours		
			Clerical	Technical	Management
II. Human Exposure and Environmental Release d/ e/	22/41	049	2.2-10.8	-	-
A. Industrial Sites Controlled by the Submitter	22/41	054	-	-	1.1-3.2
1. Process Information	22/41	054	-	0.5-2.2	-
2. Block Diagram	11/41	027	-	0.3-6.5	-
3. Occupational Exposure					
3.1-3.2 Identity of Site and Occupational Exposure at Site d/	16/41	039	-	0.8-6.2	-
3.3-3.5 Direct Exposure, Physical State, and Other Substances d/	14/41	034	-	0.7-5.4	-
4. Environmental Release and Disposal d/	15/41	036	-	0.4-4.3	-
B. Industrial Sites Controlled by Others	5/41	012	-	-	0-0.2
1. Process Information--Identity of Site	2/41	005	-	0-0.1	-
2. Process Description	4/41	010	-	0-1.4	-
3. Occupational Exposure	5/41	012	-	0-2.4	-
4. Environmental Release and Disposal	2/41	005	-	0-0.4	-
C. Consumer and Commercial User Exposure	7/41	017	-	-	0-0.3
1. Table--Route, Frequency and Number Exposed	7/41	017	-	0-2.7	-
2. Exposure Levels	0/41	0	-	-	-
3. Product Aspect Affecting Consumer Exposure	7/41	017	-	0-0.7	-
4. Byproducts of Use	0/41	0	-	0	-

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d/At least some information provided.
e/Taken as maximum number of applicants submitting any of the information in Section II.

EXHIBIT H-5
(continued)

LABOR REQUIREMENTS FOR TME APPLICATIONS

Section of Notice	Fraction of Total (41)	% of Total	Adjusted # of Hours		
			Clerical	Technical	Management
III. List of Attachments	30/41	073	0.7-5.8	-	-
A. Physical and Chemical Properties Data	25/41	061	-	2.4-9.8	0.6-2.4
B. Health and Environmental Effects Data	30/41	073	-	5.8-29.2	1.5-5.8
C-D. Notice Attachments, Confidentiality Attachments and Voluntary Attachments	-	0	-	-	-
IV. *Federal Register* Notice	30/41	073	0.7-1.5	0.7-5.8	0.7-1.5
Total (rounded)			6-28	14-101	6-24

At least some information provided.

EXHIBIT H-6

FILING COSTS FOR TME APPLICATIONS

	Clerical	Technical	Managerial
Hours to complete form	6 - 28	14 - 101	6 - 24
Dollars per hour	$17	$43	$67
Total dollars to complete form	$102 - $476	$602 - $4343	$402 - $1608
Grand Total		$1106 - $6427	

By multipling this cost by the number of TMEs expected annually, an annual form-filing cost is created. The rate at which TMEs have been arriving at the Agency has been steadily rising. In 1982 it was 73. Because we used the 1982 rate of submissions of PMNs (900) for estimating PMN costs, we use the 1982 rate for TME applications to estimate annual TME application filing costs. Based on an annual submission rate of 70 TMEs per year, the total annual filing cost to the chemical industry for TME applications is in the range of $77,420 to $449,890.

2. Confidentiality Cost for TME Applications

The confidentiality costs associated with TME applications are very similar to the estimated confidentiality costs of PMN submissions estimated using the EPA82 form. Submitters of TME applications are required to give only generic chemical identity and generic chemical use if they wish their TME to be confidential. Substantiation of confidentiality claims is not required unless an FOIA request is filed. Therefore, the cost of confidentiality depends on the frequency of FOIA requests, as well as the cost to provide generic chemical use and identity information.

In Chapter IV, the cost of providing generic chemical identity was estimated to be $80 and the cost of providing a generic chemical use $28. If all TME applicants claimed use and chemical identity confidential, then the total cost per TME would be $108. However, EPA staff estimated that only 80 percent of TME applicants claim chemical identity confidential and 60 percent claim use confidential.[2] Thus, the average TME applicant incurs costs of $81 ($80 x .8 plus $28 x .6) in claiming identity or use confidential.

The cost of substantiating confidentiality claims after a Freedom of Information Act request (FOIA) is made by a member of the public is also a factor to be considered. The best estimate of these costs was developed in the CMA survey of 1980 (CMA 1980). As reported in Chapter IV, the costs to perform all activities (i.e., providing generic names and substantiating the claims) surrounding claims is $1,755. By subtracting the expected value of the cost for providing generic use and generic chemical identity from the total cost to perform all activities related to confidentiality, the expected cost of the other activities is determined. This expected cost of $1,674 ($1,755 minus $81) is then multiplied by the percentage of TME applications for which substantiation is necessary (5.1 percent according to EPA records)[3] to obtain the average expected cost per TME for performing other confidentiality tasks -- $85. Therefore the confidentiality cost per TME application is $166 ($81 + $85). For seventy TME applications per year,[4] total annual confidentiality costs for TME applications are approximately $11,620.

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[2] EPA staff estimates.

[3] Percentage of TME applications that had FOIA requests was estimated to be 5.1 percent (phone call with Tim Knutson). Nine TME applications out of 175 had FOIA requests from 1980 through 1982.

3. Delay Costs for TME Applications

For the PMN cost analysis, delay was defined as the number of days required to complete the information requirement plus the number of days necessary for EPA's review. Delay was experienced only by those chemicals that commenced manufacture within 30 days of the expiration of the PMN review. Delay was measured as the reduction in the net present value of profits caused by earning those profits a certain number of days later than they otherwise would have been earned in the absence of PMN review.

Applying this approach to estimate the delay costs of TMEs is probably inappropriate. The fact that the company chose to submit a TME application (rather than immediately submit a PMN) generally suggests that the product is moving gradually through the research and development process, and that the TME review could have been anticipated and scheduled so as not to be on the critical path in the development process. Additional support for this hypothesis is the fact that all TMEs in the sample were submitted by large firms who have highly formalized new product development programs that usually do not move quickly. It is important to note here, that for the above reasons, the analysis may significantly overstate the cost impacts.

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[4] The annual submission rate of 70 TME applications is based on the 1982 annual number of submissions (73).

However, a case can be made that an occasional chemical must be test marketed at a particular moment and that the delay to obtain a TME would be a burden. The information provided in the sample of 41 TMEs analyzed indicates that none of the sample chemicals have this characteristic. Thus, to approximate this effect we must create a hypothetical framework. One approach is to assume that the percentage of PMNs commencing manufacture within 30 days of the close of the PMN review period is the same as the percentage of TME chemicals for which the application is on the critical path to commercialization. By further assuming that the TME pre-submission delay (see Chapters III and IV) is 30 days, as it may be for the PMN, that post-submission delay is 45 days, (the maximum review period under TSCA), and that chemicals entering the TME process have the same profit expectations on average as do all new chemicals, we can estimate the annual cost of delays as:

> .01 (reduction in present value due to 75-day delay) × $438,500 (expected profits per chemical) × .1817 (percent of PMNs commencing manufacture within 30 days) × 70 (number of TMEs per year).

The resulting product is approximately $55,800 annually. This result must be adjusted because not all TME chemicals will be successful in test marketing, and therefore will not enter commercial production and earn profits. The Snell survey in 1975 showed 3,300 new substances entering custom tests with 1,400 introduced commercially (or to the market), for a 42.4 percent success rate between custom tests and public introduction. Assuming this success rate is appropriate for TMEs, multiplying the overall $55,000 annual cost by 42.4% yields annual TME delay costs of $23,600.

4. Restrictive Action Costs

In addition to the direct filing, delay, and confidentiality costs, other costs are incurred by the TME applicant due to restrictive actions taken by EPA in the test-marketing exemption program. This section examines the restrictive actions taken on the sample 41 TME chemicals and analyzes the costs of each.

For the purposes of this analysis, restrictive action is defined as any EPA action which serves to disallow, delay, or modify the test-marketing plans of the applicant. Thus, exemption denials, TME withdrawals, and MSDS changes are considered restrictive actions. EPA requests for information leading directly to TME approval are not restrictive actions since they do not disallow or delay the test marketing plans.[5]

Of the 41 TME applications examined during this analysis, a total of four, or less than ten percent were subject to restrictive actions (two denials, one withdrawal, and one MSDS change). Adjusting this value to reflect an annual submission rate of 70 TMEs (based on the number of TMEs submitted in 1982) results in an expected level of seven restrictive actions per year. Thus, three exemption denials, two withdrawals, and two MSDS changes could be expected to occur each year. The costs of the actions can be calculated based on the quantitative analysis presented in Chapters III and IV.

Using the $438,500 to $560,400 range estimate of the lost profits per innovation (Chapter III), three denials can be estimated to cost industry

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[5] This assumes that the requested information can be generated within the 45 days allotted for the TME process. All denial and exemption decisions for the sample TME applications were rendered within the 45-day period.

$1,315,500 to $1,681,200 annually.[6] However, it is necessary to qualify these values somewhat. The costs to industry would approximate the estimates only if the test-marketed chemical would have proven to be economically viable. If on the other hand, the chemical had actually proven to be unmarketable or unfeasible, the costs to industry would be virtually zero and perhaps result in a savings.

The costs of withdrawals to industry can also be estimated using the figures above. The costs of two withdrawals would be $877,000 to $1,120,800 annually. However, in addition to the same qualifications given for the denial costs, one further qualification must be made. The withdrawal which appears in our sample occurred after the PMN for the substance was dropped and manufacture had begun. Thus although the TME was withdrawn, the restrictive action cost to industry is debatable because the chemical was being manufactured.

One of the sample TME chemicals and an estimated two annually require a change in the MSDS. Based on a draft regulatory impact analysis done for OSHA (See Chapter IV) the cost for two MSDS changes is $42.40 annually.

The total annual costs of restrictive actions in the TME program is approximately $2,192,500-$2,802,000, if all the qualifications discussed previously are ignored. However, if these quaifications (unmarketability, simultaneous PMN approval) are taken into consideration, the costs to industry are much lower.

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[6] The 90 percent confidence interval about the $438,000 estimate is $0 to close to $1,500,000 and cannot be estimated about the $560,400 figure.

D. HEALTH BENEFITS OF THE TME PROGRAM

The following section addresses the likely health implications of the restrictive actions taken by EPA on four TME chemicals of the sample 41 examined by ICF. As mentioned previously, these actions ranged from direct denials to a simple change in a MSDS. The assessments which follow contain a brief description of the TME chemical and its use, the type of health concerns raised, and the likely health impacts of the restrictive action taken. The ecotoxic effects of the four chemicals are not examined here because they were not a factor in these particular restrictive actions.

1. TME A

Total production of TME A during the test-marketing period was expected to be less than 100 kg. The submitter estimated that less than 100 persons would be exposed to the mixture during manufacture, and that several more persons would be exposed during test-marketing use. More specific exposure information and additional information on the substance's use, physical and chemical properties, and toxicity were not supplied by the applicant. EPA did express concern that the chemical resembles known mutagens and carcinogens, and that its analogs are known to have neurological effects on both the central and peripheral nervous systems (CNS and PNS). These concerns, coupled with the general lack of data provided in the TME, caused EPA to deny the exemption.

The health benefits generated in this case are difficult to quantify. Through its action, the Agency prevented the manufacture of a substance which could reasonably be expected to pose a health risk to exposed persons, and perhaps prevented some cancers, mutations or nervous system effects. In light of the very low production volume however, the number of cases avoided is expected to be very small. The general lack of data on exposure, metabolism, toxicity and dose response makes a specific estimate impossible.

2. TME B

This TME substance was intended for use in the production of a coating polymer. The chemical was expected to reach a production volume of a few hundred kilograms during one year of test marketing. EPA estimated 25 persons would be dermally exposed to a concentrated percent solution of the chemical 3-4 days during the manufacture of each batch (number of batches/year not given). An additional 50-100 persons would be dermally exposed to a dilute polymer solution during processing. Health concerns centered on the substance's eye irritation, mutagenic, and possibly carcinogenic properties. In addition, the submitter provided negligible information on worker exposure. In the absence of better information on which to base a decision, the Agency denied the TME.

Again, because exact data on exposure are missing, quantification of the health benefits derived by EPA's action is not possible. The denial may prevent some cases of eye irritation, mutation, or cancer, although this number can be anticipated to be small due to the low production level.

3. TME C

The TME substance in this case is a fabric dye. Several thousand kilograms were expected to be produced during test marketing. During manufacture one worker would be dermally exposed for 8 hours/day, 45 days/year, and during processing an additional 48 persons would be exposed

2 hours/day, for 28 to 110 days/year. Several health concerns were raised by EPA. First, the substance is highly toxic via oral routes, and is readily absorbed through the GI tract. Secondly, the chemical's metabolic breakdown products and/or analogs are known or suspected carcinogens. The Agency had reason to believe that even low levels of dermal absorption could lead to significant carcinogenic risks. In light of these concerns, EPA recommended the TME be denied. The denial recommendation was sent to OMB for review and during this time the PMN for the same substance was dropped from further review on the condition that the chemical would only be sold to customers with closed metering equipment. Manufacture commenced, and the applicant withdrew the TME because it was no longer relevant.

In this case, the health benefits associated with the actions may only be the benefits of delaying introduction for three months. It is possible that during this time exposures to workers using open dye systems were avoided, and perhaps a small number of toxic or carcinogenic health effects were avoided. However, this was the result of EPA's denial recommendation and not the specific restrictive action in this case -- i.e., the withdrawal. The health benefits of the withdrawal itself were nil because manufacture had already begun.

4. TME D

The manufacturer of the TME D intended to produce <10 kg of the substance for use as a chemical intermediate in a photographic process. Exact estimates of worker exposure were not given although, because of the low production volume, exposure was expected to be minimal. The Agency recognized the ability of the substance to become an eye irritant if converted to its free acid form, but the lack of any known toxicological activity created a basis for minimal health concern. The potential for absorption of an unavoidable impurity (an acute toxin and carcinogen by skin assay) was a point of concern for EPA. The Agency suggested that the MSDS be revised to reflect this concern. The MSDS was also reworded to convey the necessary, rather than discretionary, use of a full face piece respirator. The applicant agreed to the MSDS suggestions and the TME was granted.

The health benefits associated with the MSDS change are a possible reduction in the number of cases of eye irritation (by the free acid form) and perhaps a more cautionary use of the chemical as a result of the revised MSDS. However because of the extremely low production volume in this case, these benefits cannot be anticipated to be very great.[7]

E. CONCLUSIONS

The annual costs of the TME program are between $2,281,500 and $3,287,100 as shown in Exhibit H-7. More than 95 percent of these costs are due to restrictive actions.

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[7] A similar MSDS change accompanied the PMN of this substance (PMN D in Chapter 7). However, since the TME and PMN actions did not occur simultaneously, the health benefits from the two actions are analyzed separately. It should be noted that three of the four chemicals analyzed here were subsequently not manufactured commercially. The outcome of their PMN review was that they were not regulated during PMN review. No PMN has yet been received on the fourth chemical.

EXHIBIT H-7

ANNUAL COSTS TO INDUSTRY OF TME PROGRAM
(1981 Dollars)

Filing	$77,400 - $449,000
Confidentiality	$11,600 - $11,600
Delay	$0 - $23,600
Restrictive Actions	$2,192,500 - $2,802,000
Total	$2,281,500 - $3,287,100

As was the case with the majority of the PMNs reviewed in Appendix F, a quantitative assessment of benefits (i.e., number of cancers avoided) cannot be performed due to the lack of more specific exposure and toxicity data. The two TME applications denied (TME chemicals A and B) were both suspected mutagens and/or carcinogens and some avoidance of negative health effects can be hypothesized but not quantified. TME chemical A also represents a possible peripheral nervious system (PNS) and central nervous system (CNS) depressant, and TME chemical B a primary eye irritant. Although these possible negative effects were avoided, the health benefits must necessarily be viewed within the context of exposure and production volumes. Since both of these substance were to be produced in low quantities, the negative health benefits avoided may be quite small. A similar case exists with TME chemical D. A change in the MSDS may have generated health benefits but the production volume was so small that the benefits may be negligible for the test marketing period. TME chemical C, the substance with the most significant production volume, had very serious toxicity and carcinogenic concerns. TME C was withdrawn when production began after the PMN for the substance was "dropped" by the Agency.

Although the health benefits generated under the TME program and examined in this analysis do not appear large, they are not necessarily a reflection on the entire program. The deterrent effect (that is, firms refraining from applying for TME for substances they know to be hazardous) of the TME program has not been measured here.